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A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

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Presidential Documents

Title 3—

The President

Proclamation 10177 of April 11, 2021

National Fair Housing Month, 2021

By the President of the United States of America

A Proclamation

Exactly 1 week after the assassination of Dr. Martin Luther King, Jr., struck at the soul of our Nation, President Lyndon B. Johnson signed a landmark piece of legislation—an enduring testament to the ideals of Dr. King that enshrined a portion of his legacy in the lives and laws of the American people. Fifty-three years later, the Fair Housing Act still serves as a powerful statement about who we are as a people: the values of equality, equity, and dignity that we strive to uphold, and the places where we still have work to do to fulfill our full promise as a Nation.

The purpose of the Fair Housing Act was to put an end to inequities in our housing system and eliminate racial segregation in American neighborhoods—and guarantee that all people in America have the right to obtain the housing of their choice, free from discrimination. The law prohibits discrimination in the sale, rental, and financing of housing, and requires Federal, State, and local governments to proactively dismantle the discriminatory structures that held back people of color and other underserved populations from equitable access to the neighborhoods of their choice.

By helping to create a fairer housing system, the law seeks to do more than just open up American neighborhoods to all Americans. Access to quality housing is about more than having a roof over your head—it is the foundation for achieving better educational, employment, and health outcomes, as well as one of the most important ways that families build wealth that they can pass along across the generations. The Fair Housing Act was created at a time when Federal and State policies held that dream at arm's length from far too many Black, Brown, Native, and Asian American families through the insidious practices of redlining and lending discrimination.

Over the course of 53 years, the law has made a world of difference in the lives of countless families and communities. We have also improved upon it through the years; as a Senator, I was proud to co-sponsor the 1988 Fair Housing Act amendments that extended the law's protections to Americans with disabilities and families with children, and just 2 months ago my Administration issued a rule change to ensure that the law finally guards against discrimination targeting LGBTQ+ Americans. But the truth of the matter is that we have not fully achieved the goals of the Fair Housing Act—we still have so much work to do.

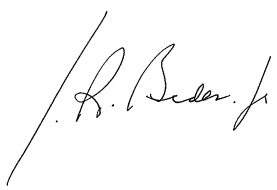
Many of our neighborhoods remain as segregated today as they were in the middle of the 20th century, and the racial wealth gap is wider now than it was when the Fair Housing Act was passed. Though our Nation has come a long way in many regards, our promise will not be fulfilled as long as anyone in America is denied a good home or a fair shot because of who they are. It is our shared duty to work together to ensure that every person has equitable access to all of the opportunities our communities provide—and that no one faces barriers to getting a good education, having quality health care, eating healthy food, or finding stable employment that allows their family to thrive solely because of where they live. This is a moral responsibility that cannot wait, particularly at a time when the

COVID–19 pandemic has further highlighted and exacerbated the lack of safe, affordable places to live for far too many people in America.

To affirm equal opportunity as the bedrock of our democracy—and to enlist the entire Federal Government to address entrenched disparities in our laws, public policies, and institutions—I signed an Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government on my first day in office. To ensure that the Federal Government continues to prioritize the right to fair housing and actively enforce our Federal civil rights laws, I also signed a Presidential Memorandum on Redressing Our Nation's and the Federal Government's History of Discriminatory Housing Practices and Policies during my first week as President. My Administration will continue our efforts to close persistent racial gaps in wages, housing, credit, lending opportunities, and access to higher education—gaps that, if closed, would add an estimated $5 trillion in gross domestic product in the American economy over the next 5 years. We are committed to doing all we can to end unlawful housing discrimination and advance equity for all underserved populations, fulfill the full promise of the Fair Housing Act, and put the American dream within reach of all Americans.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 2021 as National Fair Housing Month. I call upon the people of this Nation to help secure freedom and justice for every American by taking action to fulfill the promise made by the Fair Housing Act to ensure everyone has free and fair housing choice.

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of April, in the year of our Lord two thousand twenty-one, and of the Independence of the United States of America the two hundred and forty-fifth.



[FR Doc. 2021–07861
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Rules and Regulations

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2021–0200; Project Identifier MCAI–2020–01520–E; Amendment 39–21495; AD 2021–08–01]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG (Type Certificate Previously Held by Rolls-Royce plc) Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Rolls-Royce Deutschland Ltd & Co KG (RRD) RB211 Trent 768–60, RB211 Trent 772–60, and RB211 Trent 772B–60 model turbofan engines. This AD was prompted by maintenance that resulted in damage to certain low-pressure compressor (LPC) blades, resulting in increased susceptibility to cracking in the LPC blade root. This AD requires initial and repetitive inspections of the blade root of certain LPC blades and re-lubrication of the LPC blades and LPC disk. Depending on the results of the inspections, this AD requires replacement of the LPC blades. As a terminating action to the inspection and re-lubrication requirements, this AD requires restoration of the LPC blade as well as examination and re-lubrication of the LPC disk. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective April 30, 2021.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of April 30, 2021.

The FAA must receive comments on this AD by June 1, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov*. Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this final rule, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; website: *https://www.rolls-royce.com/contact-us.aspx*. You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759. It is also available at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0200.

Examining the AD Docket

You may examine the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0200; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for the Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Kevin M. Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov*.

SUPPLEMENTARY INFORMATION:

Background

The European Union Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2020–0253, dated November 12, 2020, to address an unsafe condition for the specified products. The MCAI states:

In-service experience has shown that certain LP compressor blades installed on Trent 700 engines may have been subjected to maintenance actions that caused damage, making the affected blades more susceptible to cracking.

This condition, if not detected and corrected, could lead to blade or disc failure and consequent engine in-flight shut-down, possibly resulting in reduced control of the aeroplane.

To address this potential unsafe condition, Rolls-Royce issued the inspection NMSB to provide inspection instructions. Rolls-Royce also issued the restoration NMSB to provide in-shop restoration instructions.

For the reasons described above, this [EASA] AD requires repetitive on-wing ultrasonic (US) inspections of the blade roots of the affected blades, subsequent re-lubrication of the affected blades and discs and, depending on findings, accomplishment of applicable corrective action(s). This [EASA] AD also requires in-shop restoration of the affected blades and discs to a serviceable condition, which constitutes terminating action for the repetitive US inspections and re-lubrications as required by this [EASA] AD.

You may obtain further information by examining the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0200.

FAA's Determination

This product has been approved by EASA and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI. The FAA is issuing this AD because the agency evaluated all the relevant information provided by EASA and has determined that the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Rolls-Royce (RR) Trent 700 Series Propulsion Systems Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AK492, Revision 1, dated November 30, 2020. This service information specifies procedures for performing initial and repetitive ultrasonic inspections of LPC blade roots, and re-lubrication of LPC blades and disks.

The FAA also reviewed RR Trent 700 Series Propulsion Systems Alert NMSB RB.211–72–AK522, Revision 1, dated

November 30, 2020. This service information specifies procedures for inspecting LPC blades, applying high intensity shot peening to the blade roots to arrest any cracks, inspecting the LPC disk to determine serviceability, and re-lubrication procedures.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

AD Requirements

This AD requires initial and repetitive inspections of the blade root of certain LPC blades and re-lubrication of the LPC blades and LPC disk. Depending on the results of the inspection, this AD requires replacement of the LPC blades. As a mandatory terminating action, at the next engine shop visit, this AD requires restoration of the LPC blades to a serviceable condition and examination and re-lubrication of the LPC disk.

Differences Between the AD and MCAI or Service Information

EASA AD 2020–0253, dated November 12, 2020, includes RRD RB211 Trent 772C–60 model turbofan engines in its Applicability section. This model engine is not included in the Applicability of this AD because it has not been type certificated in the United States.

Justification for Immediate Adoption and Determination of the Effective Date

Section 553(b)(3)(B) of the Administrative Procedure Act (APA) (5 U.S.C. 551 *et seq.*) authorizes agencies to dispense with notice and comment procedures for rules when the agency, for ''good cause,'' finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under this section, an agency, upon finding good cause, may issue a final rule without providing notice and seeking comment prior to issuance. Further, section 553(d) of the APA authorizes agencies to make rules effective in less than thirty days, upon a finding of good cause.

The FAA has found the risk to the flying public justifies waiving notice and comment prior to adoption of this rule because no domestic operators use this product. It is unlikely that the FAA will receive any adverse comments or useful information about this AD from any U.S. operator. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the foregoing reason(s), the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2021–0200 and Project Identifier MCAI–2020–01520–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this final rule.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Kevin M. Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Regulatory Flexibility Act

The requirements of the Regulatory Flexibility Act (RFA) do not apply when an agency finds good cause pursuant to 5 U.S.C. 553 to adopt a rule without prior notice and comment. Because FAA has determined that it has good cause to adopt this rule without prior notice and comment, RFA analysis is not required.

Costs of Compliance

The FAA estimates that this AD affects 0 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect LPC blades and re-lubricate LPC blade and LPC disk.	32 work-hours × $85 per hour = $2,720	$0	$2,720	$0
Restore LPC blades, examine and re-lubricate LPC disk.	128 work-hours × $85 per hour = $10,880	0	10,880	0

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the inspection. The FAA has no way of determining the number of aircraft that might need these replacements.

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace LPC blade	.25 work-hours × $85 per hour = $21.25	$116,000	$116,021.25

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866, and

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

2021–08–01 Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc): Amendment 39–21495; Docket No. FAA–2021–0200; Project Identifier MCAI–2020–01520–E.

(a) Effective Date

This airworthiness directive (AD) is effective April 30, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (Type Certificate previously held by Rolls-Royce plc) RB211 Trent 768–60, RB211 Trent 772–60, and RB211 Trent 772B–60 model turbofan engines equipped with:

(1) Low-pressure compressor (LPC) blade, with part number (P/N) FW23741 or P/N KH23403, and a serial number (S/N) listed in Appendix 1 of Rolls-Royce (RR) Trent 700 Series Propulsion Systems Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AK492, Revision 1, dated November 30, 2020 (NMSB RB.211–72–AK492), installed; or

(2) LPC disk, with P/N FK22541, P/N FW16259 or P/N KH20338, and an S/N listed in Appendix 2 of NMSB RB.211–72–AK492.

(d) Subject

Joint Aircraft System Component (JASC) code 7240, Turbine Engine Combustion Section.

(e) Unsafe Condition

This AD was prompted by maintenance that resulted in damage to certain LPC blades, resulting in increased susceptibility to cracking in the blade root. The FAA is issuing this AD to prevent failure of the LPC blade and the LPC disk. The unsafe condition, if not addressed, could result in engine in-flight shut-down and reduced control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Within 200 engine flight cycles (FCs) after the effective date of this AD, perform an initial on-wing ultrasonic inspection of the blade root of each LPC blade using the Accomplishment Instructions, paragraph 3.A.(3)(a) through (c) of NMSB RB.211–72–AK492.

(2) Within 200 engine FCs after the effective date of this AD, re-lubricate each LPC blade and LPC disk using the Accomplishment Instructions, paragraph 3.A.(4) of NMSB RB.211–72–AK492.

(3) Repeat the inspection of each LPC blade and the re-lubrication of each LPC blade and LPC disk required by paragraphs (g)(1) and (2) of this AD at intervals not to exceed 350 engine FCs since the last inspection and re-lubrication.

(4) If, during any inspection required by paragraph (g)(1) or (3) of this AD, an LPC blade is found with unacceptable indications as specified in Appendix 4, paragraph 3 of NMSB RB.211–72–AK492, before next flight, remove and replace the LPC blade with a part eligible for installation.

(h) Mandatory Terminating Action

As a mandatory terminating action to the inspections and re-lubrications required by paragraphs (g)(1) through (3) of this AD, at the next engine shop visit after the effective date of this AD, restore the LPC blades to a serviceable condition and examine and re-lubricate the LPC disk using the Accomplishment Instructions, paragraph 3.A or 3.B of RR Trent 700 Alert NMSB RB.211–72–AK522, Revision 1, dated November 30, 2020.

(i) Definitions

(1) For the purposes of this AD, an ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges, with the exception of the separation of engine flanges solely for the purpose of transporting the engine without subsequent maintenance.

(2) For the purposes of this AD, a part eligible for installation is an LPC blade, with:

(i) A P/N FW23741 or P/N KH23403, with an S/N listed in Appendix 1 of RR Trent 700 Series Propulsion Systems Alert NMSB RB.211–72–AK492, that has passed the inspections required by paragraph (g)(1) or (3) of this AD, or has zero flight cycles since new; or

(ii) A P/N FW23741 or P/N KH23403, with an S/N that is not listed in Appendix 1 of RR Trent 700 Series Propulsion Systems Alert NMSB RB.211–72–AK492.

(j) Credit for Previous Actions

(1) You may take credit for the initial inspections and re-lubrications required by paragraphs (g)(1) and (2) of this AD if you performed these actions before the effective date of this AD using RR Trent 700 Series Propulsion Systems Alert NMSB RB.211–72–AK492, Initial Issue, dated October 2, 2020.

(2) You may also take credit for the restoration of the LPC blades to a serviceable condition and examination and re-lubrication of the LPC disk required by paragraph (h) of this AD if you performed these actions before the effective date of this AD using RR Trent 700 Series Propulsion Systems Alert NMSB

RB.211–72–AK522, Initial Issue, dated October 2, 2020.

(k) No Reporting Requirements

The reporting requirements specified in Appendix 4, paragraph 3 of NMSB RB.211–72–AK492 are not required by this AD.

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ECO Branch, send it to the attention of the person identified in Related Information. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(m) Related Information

For more information about this AD, contact Kevin M. Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov.*

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Rolls-Royce (RR) Trent 700 Series Propulsion Systems Alert Non-Modification Service Bulletin (NMSB) RB.211–72–AK492, Revision 1, dated November 30, 2020.

(ii) RR Trent 700 Series Propulsion Systems Alert NMSB RB.211–72–AK522, Revision 1, dated November 30, 2020.

(3) For service information identified in this AD, contact Rolls-Royce plc, P.O. Box 31, Derby, DE24 8BJ, United Kingdom; phone: +44 (0)1332 242424; website: *https://www.rolls-royce.com/contact-us.aspx.*

(4) You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (781) 238–7759.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email: *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on April 8, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–07567 Filed 4–14–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–1193; Airspace Docket No. 20–AAL–28]

RIN 2120–AA66

Establishment of Class E Airspace; Hughes, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace extending upward from 700 feet above the surface at Hughes Airport, Hughes, AK, to accommodate new area navigation (RNAV) procedures. This action will ensure the safety and management of instrument flight rules (IFR) operations within the National Airspace System.

DATES: Effective 0901 UTC, June 17, 2021. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order 7400.11E, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA).

For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Richard Roberts, Federal Aviation Administration, Western Service Center, Operations Support Group, 2200 S 216th Street, Des Moines, WA 98198; telephone (206) 231–2245.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code (U.S.C.). Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it will establish Class E airspace to support new RNAV procedures at Hughes Airport, Hughes AK, for the safety and management of aircraft within the National Airspace System.

History

The FAA published a notice of proposed rulemaking in the **Federal Register** (86 FR 6279; January 21, 2021) for Docket No. FAA–2020–1193 to establish Class E airspace extending upward from 700 feet above the earth at Hughes Airport, Hughes AK, in support of IFR operations. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. Two comments were received. One commenter supported the establishment of airspace in support of IFR operations. The other commenter stated that the new airspace would cause people to stay at an unsafe altitude when flying in poor weather. The FAA does not concur. This new volume of airspace does not preclude aircraft from flying in this area, but will provide additional protection in marginal weather. The floor of the new airspace will be 700 feet AGL versus 1,200 feet AGL. It will expand the basic VFR weather minimums visibility requirement, in this airspace, from 1 mile to 3 miles and the clearance from clouds will change from clear of clouds to 500 feet below the clouds, 1,000 feet above and 2,000 feet horizontally. The new airspace expands the opportunity for operations in both instrument and visual meteorological conditions and increases the efficiency of the airport and safety of operations in the area.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020 and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this

document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

The FAA is amending 14 CFR part 71 by establishing Class E airspace extending upward from 700 feet above the surface at Hughes Airport, Hughes AK.

The Class E airspace will be established within a 3.8-mile radius of the airport and within an area 2 miles each side of the 194° bearing extending from the airport 6.4 miles south. This area will protect aircraft on approach to runway 36 as they descend through 1,500 feet above ground level (AGL). In addition, an extension in the shape of a dogleg will be established 1.8 miles each side of the 14° bearing extending from the 3.8-mile radius to 6 miles north of the airport and then 1.8 miles each side of the 39° bearing from a point in space, lat. 66°08′14″ N, long. 154°12′17″ W, forming an angle that extends from the 3.8-mile radius northeast 9.5 miles from the airport. This section will protect aircraft on approach to runway 18 descending through 1,500 feet AGL and those aircraft on departure until reaching 1,200 feet AGL.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order (E.O.) 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July, 21, 2020 and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace.

* * * * *

AAL AK E5 Hughes, AK [New]

Hughes Airport, AK
(66°02′21″ N, 154°15′53″ W)

That airspace within a 3.8-mile radius of Hughes Airport, AK, and that airspace 2 miles each side of the 194° bearing extending from the 3.8-mile radius south 6.4 miles from the airport, and that airspace extending from the 3.8-mile radius beginning 1.8 miles west of the 14° bearing to lat. 66°08′55″ N, long. 154°16′32″ W to lat. 66°12′15″ N, long. 154°10′06″ W to lat. 66°10′03″ N, long. 154°03′03″ W to lat. 66°07′23″ N, long. 154°08′18″ W to the point on the 3.8-mile radius 1.8 miles east of the 14° bearing.

Issued in Des Moines, Washington, on April 9, 2021.

B.G. Chew,

Acting Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2021–07667 Filed 4–14–21; 8:45 am]

BILLING CODE 4910–13–P

INTERNATIONAL TRADE COMMISSION

19 CFR Part 208

Implementing Rules for the United States-Mexico-Canada Agreement Implementation Act; Correction

AGENCY: United States International Trade Commission.

ACTION: Final rule; correction

SUMMARY: The United States International Trade Commission (Commission) is correcting a final rule that appeared in the **Federal Register** on April 8, 2021. The rule concerns the practices and procedures for investigations of United States-Mexico cross-border long-haul trucking services provided for in the United States-Mexico-Canada Agreement Implementation Act.

DATES: Effective May 10, 2021.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, United States International Trade Commission, telephone (202) 205–2000, or William Gearhart, Office of the General Counsel, United States International Trade Commission, telephone (202) 205–3091. Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its website at *https://www.usitc.gov.*

SUPPLEMENTARY INFORMATION: In FR Doc. 2021–07181 appearing on page 18183 in the **Federal Register** on April 8, 2021, the following correction is made:

§ 208.5 [Corrected]

■ On page 18185 in the second column, in part 208, the instruction ''2. Amend § 208.5 by revising paragraph (e)(i)(vi) to read as follows:'' is corrected to read ''2. Amend § 208.5 by revising paragraph (e)(1)(vi) to read as follows:''

By order of the Commission.

Issued: April 9, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–07665 Filed 4–14–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF THE INTERIOR

Bureau of Ocean Energy Management

30 CFR Parts 550 and 553

[Docket ID: BOEM–2021–0006]

RIN 1010–AE06

2021 Civil Penalties Inflation Adjustments for Oil, Gas, and Sulfur Operations in the Outer Continental Shelf

AGENCY: Bureau of Ocean Energy Management, Interior.

ACTION: Final rule.

SUMMARY: This final rule implements the 2021 inflation adjustments to the maximum daily civil monetary penalties contained in the Bureau of Ocean Energy Management (BOEM) regulations for violations of the Outer Continental Shelf Lands Act (OCSLA) and the Oil Pollution Act of 1990 (OPA), pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (FCPIAA Improvements Act) and relevant Office of Management and Budget (OMB) guidance. The 2021 adjustment multiplier of 1.01182 accounts for one year of inflation from October 2019 through October 2020.

DATES: This rule is effective on April 15, 2021.

FOR FURTHER INFORMATION CONTACT: Deanna Meyer-Pietruszka, Chief, Office of Policy, Regulation, and Analysis, Bureau of Ocean Energy Management, at (202) 208–6352 or by email at *Deanna.Meyer-Pietruszka@boem.gov.*

SUPPLEMENTARY INFORMATION:

I. Legal Authority

OCSLA authorizes the Secretary of the Interior (the Secretary) to impose a daily civil monetary penalty for a violation of OCSLA or its implementing regulations, leases, permits, or orders and directs the Secretary to adjust the maximum penalty at least every three years to reflect any inflation increase in the Consumer Price Index. 43 U.S.C. 1350(b)(1). Similarly, OPA authorizes civil monetary penalties for failure to comply with OPA's financial responsibility provisions or its implementing regulations. 33 U.S.C. 2716a(a). OPA does not include a maximum daily civil penalty inflation adjustment provision. Id.

The FCPIAA Improvements Act [1] requires that Federal agencies publish inflation adjustments to their civil monetary penalties in the **Federal Register** not later than January 15 annually.[2] Public Law 114–74, 701(b)(1). The purposes behind these inflation adjustments are to maintain the deterrent effect of civil penalties and to further the policy goals of the underlying statutes. Federal Civil Penalties Inflation Adjustment Act of 1990, Public Law 101–410, 2 (codified at 28 U.S.C. 2461 note).

II. Background

BOEM implemented the 2020 inflation adjustment for its civil monetary penalties through a final rule, ''2020 Civil Penalties Inflation Adjustments for Oil, Gas, and Sulfur Operations in the Outer Continental Shelf,'' published in the **Federal Register** on February 7, 2020, which accounted for inflation for the twelve month period between October 2018 and October 2019. 85 FR 7218 (February 7, 2020).

For 2021, OMB issued guidance that explains agency statutory responsibilities for identifying applicable civil monetary penalties and performing the annual adjustment; publishing revisions to regulations to implement the adjustment in the **Federal Register**; applying adjusted penalty levels; and performing agency oversight of inflation adjustments. ''Implementation of Penalty Inflation Adjustments for 2021, Pursuant to the Federal Civil Penalties Inflation Adjustment Act (FCPIAA) Improvements Act of 2015,'' OMB Memorandum M–21–10, December 23, 2020 (OMB M–21–10), available at *https://www.whitehouse.gov/wp-content/uploads/2020/12/M-21-10.pdf.*

Through this final rule, pursuant to the FCPIAA Improvements Act and OMB M–21–10, BOEM is implementing the 2021 inflation adjustments to the OCSLA and OPA maximum daily civil monetary penalties. A proposed rule is unnecessary. The FCPIAA Improvements Act expressly exempts annual civil penalty inflation adjustments from the Administrative Procedure Act's (APA) notice of proposed rulemaking, public comment, and standard effective date provisions. FCPIAA Improvements Act, Public Law 114–74, 701(b)(1)(D); APA, 5 U.S.C. 553.[3]

III. Calculation of 2021 Adjustments

OMB issued guidance to Federal agencies on implementing the 2021 annual civil monetary penalties inflation adjustments, including the adjustment multiplier: 1.01182. OMB M–21–10; FCPIAA Improvements Act, sec. 701(b)(4).[4] In accordance with the FCPIAA Improvements Act and OMB M–21–10, BOEM determined the OCSLA and OPA maximum daily civil monetary penalties require annual inflation adjustments and is issuing this final rule adjusting those penalty amounts for inflation through October 2020.

For 2021, BOEM multiplied the current OCSLA maximum daily civil penalty of $45,463 by the multiplier 1.01182 to equal $46,000.37, rounded to the nearest cent ($45,463 × 1.01182 = $46,000.37). The FCPIAA Improvements Act requires that the resulting amount then be rounded to the nearest dollar.

[1] The FCPIAA Improvements Act amended the Federal Civil Penalties Inflation Adjustment Act of 1990. Public Law 101–410 (codified at 28 U.S.C. 2461 note).

[2] Under the FCPIAA Improvements Act, Federal agencies were required to adjust their civil monetary penalties for inflation with an initial ''catch-up'' adjustment through an interim final rulemaking in 2016 and are required to make subsequent inflation adjustments not later than January 15 annually, beginning in 2017. Public Law 114–74, 701(b)(1).

[3] Specifically, Congress directed that agencies adjust civil monetary penalties ''notwithstanding section 553 of title 5, United States Code [Administrative Procedure Act (APA)],'' which generally requires prior notice of proposed rulemaking, opportunity for public comment on proposed rulemaking, and publication of a final rule at least 30 days before its effective date. FCPIAA Improvements Act, sec. 701(b)(1)(D); APA, 5 U.S.C. 553. OMB confirmed this interpretation of the FCPIAA Improvements Act. OMB M–21–10 at 3 (''This means that the public procedure the APA generally requires—notice, an opportunity for comment, and a delay in effective date—is not required for agencies to issue regulations implementing the annual adjustment.'').

[4] The annual inflation adjustment is based on the percent change between the Consumer Price Index for All Urban Consumers (CPI–U) for the October preceding the date of the adjustment and the prior year's October CPI–U. Consistent with OMB M–21–10, the 2021 multiplier can be calculated by dividing the October 2020 CPI–U by the October 2019 CPI–U. In this case, October 2020 CPI–U (260.388)/October 2019 CPI–U (257.346) = 1.01182.

Accordingly, the 2021 adjusted OCSLA maximum daily civil monetary penalty is $46,000.

For 2021, BOEM multiplied the current OPA maximum daily civil penalty amount of $48,192 by the multiplier 1.01182 to equal $48,761.63, rounded to the nearest cent ($48,192 × 1.01182 = $48,761.63). The FCPIAA Improvements Act requires that the resulting amount then be rounded to the nearest dollar. Accordingly, the 2021 adjusted OPA maximum daily civil monetary penalty is $48,762.

The adjusted penalty amounts take effect immediately upon publication of this rule. Under the FCPIAA Improvements Act, the adjusted amounts apply to civil penalties assessed after the date the increase takes effect, even if the associated violation predates the increase.

This table summarizes BOEM's 2021 maximum daily civil monetary penalties for each OCSLA and OPA violation:

CFR citation	Description of the penalty	Current maximum penalty	Multiplier	Adjusted maximum penalty
30 CFR 550.1403 (OCSLA)	Failure to comply per day per violation	$45,463	1.01182	$46,000
30 CFR 553.51(a) (OPA)	Failure to comply per day per violation	48,192	1.01182	48,762

IV. Procedural Requirement

A. Statutes

1. National Environmental Policy Act

This rule does not constitute a major Federal action significantly affecting the quality of the human environment. A detailed statement under the National Environmental Policy Act (NEPA, 42 U.S.C. 4321 *et seq.*) is not required because, as a regulation of an administrative nature, this rule is covered by a categorical exclusion. See 43 CFR 46.210(i). BOEM also has determined that the rule does not implicate any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. Therefore, a detailed statement under NEPA is not required.

2. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA, 5 U.S.C. 601 *et seq.*) requires an agency to prepare a regulatory flexibility analysis for all rules unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The RFA applies only to rules for which an agency is required to first publish a proposed rule. See 5 U.S.C. 603(a) and 604(a). The FCPIAA Improvements Act expressly exempts these annual inflation adjustments from the requirement to publish a proposed rule for notice and comment. FCPIAA Improvements Act, Public Law 114–74, 701(b)(1)(D); OMB M–21–10 at 3. Thus, the RFA does not apply to this rulemaking.

3. Paperwork Reduction Act

This rule does not contain information collection requirements, and, therefore, a submission to OMB under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) is not required.

4. Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or tribal governments, or on the private sector, of more than $164 million per year. The rule does not have a significant or unique effect on State, local, or tribal governments, or on the private sector. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

5. Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2). This rule:

(a) Will not have an annual effect on the economy of $100 million or more;

(b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and

(c) Will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

6. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*) and OMB guidance,[5] the Office of Information and Regulatory Affairs (OIRA) determined that this rule is not a major rule, as defined by the act.[6] Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, Fall 2020 Unified Agenda of Regulatory and Deregulatory Actions, Department of the Interior, RIN 1010–AE06, available at: *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202004&RIN=1010-AE06.*

[5] Office of Mgmt. & Budget, Exec. Office of the President, OMB M–19–14, Guidance on Compliance with the Congressional Review Act (2019).

[6] 5 U.S.C. 804(2).

B. Executive Orders (E.O.)

1. Governmental Actions and Interference with Constitutionally Protected Property Rights (E.O. 12630)

This rule does not effect a taking of private property or otherwise have takings implications under E.O. 12630. Therefore, a takings implication assessment is not required.

2. Regulatory Planning and Review (E.O. 12866); Improving Regulation and Regulatory Review (E.O. 13563)

E.O. 12866 provides that OIRA will review all significant rules. OIRA has determined that this rule is not significant. See OMB M–21–10 at 3.

E.O. 13563 reaffirms the principles of E.O. 12866, while calling for improvements in the Nation's regulatory system to reduce uncertainty and to promote predictability and the use of the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 further emphasizes that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. However, there is no science being used in this rulemaking, as Congress directed agencies to adjust the maximum daily civil penalty amounts using a particular equation, and BOEM does not have discretion to use any other factor in the adjustment. BOEM has developed this rule in a manner consistent with these E.O. 13563 requirements, to the extent relevant and feasible given the limited discretion provided agencies under the FCPIAA Improvements Act.

3. Civil Justice Reform (E.O. 12988)

This rule complies with the requirements of E.O. 12988. Specifically, this rule:

(a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and

(b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

4. Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. To the extent State and local governments have a role in outer continental shelf activities, this rule will not affect that role. Therefore, a federalism summary impact statement is not required.

5. Consultation and Coordination With Indian Tribal Governments (E.O. 13175)

The Department of the Interior and BOEM strive to strengthen their government-to-government relationships with Indian tribes through a commitment to consultation with Indian tribes and recognition of their right to self-governance and tribal sovereignty. BOEM has evaluated this rule under the Department of the Interior's consultation policy, under Departmental Manual part 512 chapters 4 and 5, and under the criteria in E.O. 13175 and determined that this rule has no substantial direct effects on Federally-recognized Indian tribes or Alaska Native Claims Settlement Act (ANCSA) Corporations, and that consultation under the Department of the Interior's and BOEM's tribal and ANCSA consultation policies is not required.

6. Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (E.O. 13211)

This rule is not a significant energy action under the definition in E.O. 13211. Therefore, a statement of energy effects is not required.

List of Subjects

30 CFR Part 550

Administrative practice and procedure, Continental shelf, Environmental impact statements, Environmental protection, Federal lands, Government contracts, Investigations, Mineral resources, Oil and gas exploration, Outer continental shelf, Penalties, Pipelines, Reporting and recordkeeping requirements, Rights-of-way, Sulfur.

30 CFR Part 553

Administrative practice and procedure, Continental shelf, Financial responsibility, Liability, Limit of liability, Oil and gas exploration, Oil pollution, Outer continental shelf, Penalties, Pipelines, Reporting and recordkeeping requirements, Rights-of-way, Surety bonds, Treasury securities.

Laura Daniel-Davis,

Principal Deputy Assistant Secretary, Land and Minerals Management.

The action taken herein is pursuant to an existing delegation of authority.

For the reasons stated in the preamble, BOEM amends 30 CFR parts 550 and 553 as follows:

PART 550—OIL AND GAS AND SULPHUR OPERATIONS IN THE OUTER CONTINENTAL SHELF

■ 1. The authority citation for part 550 continues to read as follows:

Authority: 30 U.S.C. 1751; 31 U.S.C. 9701; 43 U.S.C. 1334.

■ 2. Revise § 550.1403 to read as follows:

§ 550.1403 What is the maximum civil penalty?

The maximum civil penalty is $46,000 per day per violation.

PART 553—OIL SPILL FINANCIAL RESPONSIBILITY FOR OFFSHORE FACILITIES

■ 3. The authority citation for part 553 continues to read as follows:

Authority: 33 U.S.C. 2704, 2716; E.O. 12777, as amended.

■ 4. In § 553.51, revise paragraph (a) to read as follows:

§ 553.51 What are the penalties for not complying with this part?

(a) If you fail to comply with the financial responsibility requirements of OPA at 33 U.S.C. 2716 or with the requirements of this part, then you may be liable for a civil penalty of up to $48,762 per COF per day of violation (that is, each day a COF is operated without acceptable evidence of OSFR).

* * * * *

[FR Doc. 2021–07722 Filed 4–14–21; 8:45 am]

BILLING CODE 4310–MR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0195]

RIN 1625–AA00

Safety Zone; San Diego Bay, San Diego, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters within a 100-yard radius of the USS BONHOMME RICHARD while being towed through San Diego Bay, San Diego, CA. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with the dead ship tow of the USS BONHOMME RICHARD as it is transiting from Pier 2 Naval Base San Diego to the San Diego Bay Channel Entrance. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port San Diego.

DATES: This rule is effective from 6 a.m. until 7:30 p.m. on April 15, 2021.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0195 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant John Santorum, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone 619–278–7656, email *MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule

without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. This safety zone is required to protect the maritime public and the surrounding waterways from hazards associated with the dead ship tow of the USS BONHOMME RICHARD. It is impracticable to publish an NPRM because the Coast Guard must establish this safety zone by April 15, 2021. The Coast Guard lacks sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because this rule is needed to protect mariners, commercial and recreational waterway users, and marine environment from dangers associated with the dead ship tow of the USS BONHOMME RICHARD on April 15, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port San Diego (COTP) has determined that potential hazards associated with the dead ship tow of the USS BONHOMME RICHARD on April 15, 2021, will be a safety concern for anyone in the vicinity of the USS BONHOMME RICHARD and tugs. Fuel on the USS BONHOMME RICHARD will remain on board during the transit. Due to the increased public awareness associated with the USS BONHOMME RICHARD, a potential for media presence and an increase of recreational vessel traffic presents a significant hazard to the operation. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the USS BONHOMME RICHARD is being towed from Pier 2 Naval Base San Diego to the San Diego Bay Channel Entrance.

IV. Discussion of the Rule

This rule establishes a safety zone from 6 a.m. until 7:30 p.m. on April 15, 2021. The safety zone will cover all navigable waters within a 100-yard radius of the USS BONHOMME RICHARD while being towed through San Diego Bay, San Diego, CA. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the USS BONHOMME RICHARD is being dead ship towed from Pier 2 Naval Base San Diego to the San Diego Bay Channel Entrance. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and limited duration of the safety zone. This safety zone impacts a small area of the San Diego Bay for a limited period as the USS BONHOMME RICHARD transits the bay and on a day when vessel traffic is normally low. Furthermore, vessel traffic can safely transit around the safety zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In

particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a moving safety zone that will prohibit entry within a 100-yard radius of the USS BONHOMME RICHARD while being towed from Pier 2 Naval Base San Diego to the San Diego Bay Channel Entrance. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T11–053 to read as follows:

§ 165.T11–053 Safety Zone; San Diego Bay, San Diego, CA.

(a) *Location.* The following area is a safety zone. All waters of San Diego Bay, from surface to bottom within a 100-yard radius of the USS BONHOMME RICHARD while transiting from Pier 2 Naval Base San Diego to the San Diego Bay Channel Entrance.

(b) *Definitions.* As used in this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port San Diego (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF Channel 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(d) *Enforcement period.* This section will be enforced from 6 a.m. to 7:30 p.m. on April 15, 2021.

Dated: April 1, 2021.

T.J. Barelli,

Captain, U.S. Coast Guard, Captain of the Port Sector San Diego.

[FR Doc. 2021–07753 Filed 4–14–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

43 CFR Part 51

[Docket No. DOI–2020–0001; 201D0102DM, DS6CS00000, DLSN00000.000000, DX6CS25]

RIN 1093–AA27

Procedures for Issuing Guidance Documents

AGENCY: Office of the Secretary, Interior.

ACTION: Final rule; rescission of regulations.

SUMMARY: On October 26, 2020, the Department of the Interior (Department) published an interim final rule implementing an Executive order (E.O.), entitled ''Promoting the Rule of Law Through Improved Agency Guidance Documents.'' The E.O. defined guidance documents and required Federal agencies to finalize regulations or amend existing regulations to establish processes and procedures for issuing guidance documents, among other actions. In accordance with the E.O. entitled, ''Revocation of Certain Executive Orders Concerning Federal Regulation'' issued by President Biden on January 20, 2021, this final rule rescinds the Department's interim final rule.

DATES: This rule is effective April 15, 2021.

FOR FURTHER INFORMATION CONTACT: Bivan Patnaik, Deputy Director of Regulatory Affairs, Office of the Executive Secretariat and Regulatory Affairs, by phone at 202–208–3181 or via the Federal Relay Service at 800–877–8339, or via email account *guidance_document@ios.doi.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

On October 26, 2020, the Department of the Interior published an interim final rule on guidance (85 FR 67666) implementing E.O. 13891, ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' signed by President Trump on October 9, 2019. As required by the E.O., the rule contained the Department's procedural requirements governing the development, review, and clearance of guidance documents; the processes for the public to petition for withdrawal or modification of a particular guidance document, including designating the officials to whom petitions should be directed; and the procedures for review and approval of significant guidance documents.

On January 20, 2021, President Biden issued E.O. 13992, ''Revocation of Certain Executive Orders Concerning Federal Regulation,'' which, among other actions, revoked E.O. 13891 and directed agencies to promptly take steps to rescind any rules implementing or enforcing the executive orders. The January 20, 2021, E.O. states that it is the policy of the Administration ''to use available tools to confront the urgent challenges facing the Nation, including the coronavirus disease 2019 (COVID–19) pandemic, economic recovery, racial justice, and climate change. To tackle these challenges effectively, executive departments and agencies (agencies) must be equipped with the flexibility to use robust regulatory action to address national priorities. This E.O. revokes harmful policies and directives that

threaten to frustrate the Federal Government's ability to confront these problems and empowers agencies to use appropriate regulatory tools to achieve these goals.'' After consideration and review, the Department concluded that the October 26, 2020, interim final rule on our procedural requirements deprives the Department and subordinate Bureaus and Offices of the necessary flexibility in determining when and how best to issue public guidance based on particular facts and circumstances. The interim final rule also unduly restricts the Department's ability to provide timely guidance on which the public can confidently rely. Therefore, in accordance with President Biden's January 20, 2021, E.O., the Department is issuing this final rule, which rescinds the October 26, 2020, interim final rule.

In accordance with OMB memorandum ''Guidance for Regulatory Review'' (M–09–13), the Office of Management and Budget will continue to review all agency actions and documents subject to the Office of Information and Regulatory Affairs review under E.O. 12866. These reviews include policy and guidance documents that OMB determines to be significant.

In order to ensure transparency, the single, searchable, indexed website (*www.doi.gov/elips/browse*) that contains all of the Department's guidance documents and was made available to the public on February 28, 2020 (85 FR 12009), will remain active. However, the website will be revised to remove any references to E.O. 13891.

II. Final Rule

The Department has determined that this rule is suitable for final rulemaking. The rule rescinds the October 26, 2020, revisions to the Department's existing procedures and associated implementation as it related to the development, review, and clearance of guidance documents as directed by E.O. 13891. As with the October 26, 2020, interim final rule, the Department is not required to engage in a notice and comment process to issue this rule under the Administrative Procedure Act. See 5 U.S.C. 553(b)(3)(B). Furthermore, because this rule is procedural rather than substantive; the normal requirement of 5 U.S.C. 553(d) that a rule not be effective until at least 30 days after publication in the **Federal Register** is inapplicable.

List of Subjects in 43 CFR Part 51

Administrative practice and procedure, Executive orders.

PART 51—[REMOVED]

■ For the reasons discussed in the preamble, and under the authority of 5 U.S.C. Chapter 5, Subchapter II; Chapter 7, the Department of the Interior amends 43 CFR by removing part 51.

This action is taken pursuant to delegated authority.

Rachael S. Taylor,

Principal Deputy Assistant Secretary—Policy, Management and Budget.

[FR Doc. 2021–07685 Filed 4–14–21; 8:45 am]

BILLING CODE 4334–63–P

Proposed Rules

Federal Register
Vol. 86, No. 71
Thursday, April 15, 2021

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1220

[Document No. AMS–LP–20–0085]

Soybean Promotion and Research: Adjusting Representation on the United Soybean Board

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would adjust the number of members on the United Soybean Board (Board) to reflect changes in production levels that have occurred since the Board was last reapportioned in 2018. As required by the Soybean Promotion, Research, and Consumer Information Act (Act), membership on the Board is reviewed every 3 years and adjustments are made accordingly. This proposed change would result in a decrease in Board membership for one State, decreasing the total number of Board members from 78 to 77. These changes would be reflected in the Soybean Promotion and Research Order (Order) and would be effective with the Secretary of Agriculture's (Secretary) appointments for terms in the year 2022. This proposed rule would also correct the number of States and units to the Order. Technical corrections to the regulations would adjust the number of States and units from 30 to 31.

DATES: Submit comments on or before June 14, 2021.

ADDRESSES: Comments should be posted online at *www.regulations.gov.* Comments received will be posted without change, including any personal information provided. All comments should reference the docket number AMS–LP–20–0085, the date of submission, and the page number of this issue of the **Federal Register**. Comments may also be sent to Sarah Aswegan, Agricultural Marketing Specialist, Research and Promotion Division; Livestock and Poultry Program; AMS; USDA, Room 2627–S, STOP 0251, 1400 Independence Avenue SW, Washington, DC 20250–0251. Comments will be made available for public inspection at the above address during regular business hours or via the internet at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Sarah Aswegan, Research and Promotion Division, at (515) 201–5190; or by email at *Sarah.Aswegan@usda.gov.*

SUPPLEMENTARY INFORMATION:

Executive Orders 12866 and 13563

Executive Orders (E.O.) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule does not meet the definition of a significant regulatory action contained in section 3(f) of E.O. 12866 and is therefore not subject to review by the Office of Management and Budget (OMB).

Executive Order 12988

This proposed rule has been reviewed under E.O. 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

Section 11 of the Act (7 U.S.C. 2910) provides that nothing in the Act may be construed to preempt or supersede any other program relating to soybean promotion organized and operated under the laws of the U.S. or any State. There are no administrative proceedings that must be exhausted prior to any judicial challenge to the provisions of this rule.

Executive Order 13175

This action has been reviewed in accordance with the requirements of E.O. 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation would not have substantial and direct efforts on Tribal governments or significant Tribal implications.

Paperwork Reduction Act

In accordance with OMB regulations (5 CFR part 1320) that implement the Paperwork Reduction Act of 1995 (44 U.S.C. part 35), the information collection and recordkeeping requirements contained in the Order and accompanying Rules and Regulations have previously been approved by OMB and were assigned OMB control number 0581–0093.

Background and Proposed Action

The Board was initially appointed on July 11, 1991, pursuant to the provisions of the Act (7 U.S.C. 6301–6311), and the Order (7 CFR part 1220) issued thereunder. The Order established an initial Board with 60 members, composed of soybean producers. For purposes of establishing the Board, the United States was divided into 31 States and geographical units. Representation on the Board from each unit was determined by the level of production in each unit.

Reapportionment

Section 1220.201(c) of the Order provides that at the end of each 3-year period, the Board shall review soybean production levels in the geographic units throughout the United States. Section 1220.130 of the Order defines a unit as each State, or group of States, which is represented on the Board. The Board may recommend to the Secretary modification in the levels of production necessary for Board membership for each unit.

Section 1220.201(d) of the Order provides that at the end of each 3-year period, the Secretary must review the volume of production of each unit and adjust the boundaries of any unit and the number of Board members from each such unit as necessary to conform with the criteria set forth in § 1220.201(e): (1) To the extent practicable, States with annual average soybean production of less than 3 million bushels shall be grouped into geographically contiguous units, each of which has a combined production level equal to or greater than 3 million bushels, and each such group shall be entitled to at least one member on the Board; (2) units with at least 3 million bushels, but fewer than 15 million bushels shall be entitled to one board member; (3) units with 15 million bushels or more but fewer than 70

million bushels shall be entitled to two Board members; (4) units with 70 million bushels or more but fewer than 200 million bushels shall be entitled to three Board members; and (5) units with 200 million bushels or more shall be entitled to four Board members.

The Board was last reapportioned in 2018. The total Board membership increased from 73 to 78 members, with Alabama, Kentucky, North Dakota, South Dakota, and Tennessee each gaining one additional member. The final rule was published in the **Federal Register** (83 FR 53365) on October 23, 2018. This change was effective with the 2019 appointments.

This proposed rule would decrease total membership on the Board from 78 to 77. Production data for years 2015–2019 (excluding the crops in years in which production was the highest and in which production was the lowest in each State) as reported by USDA's National Agricultural Statistics Service (NASS). This change would not affect the number of geographical units.

This proposed rule would adjust representation on the Board as follows:

State	Current representation	Proposed representation
Alabama	2	1

Board adjustments as proposed by this rulemaking would become effective, if adopted, with the 2022 appointment process.

This proposed rule would also correct the number of States and units to the Order. During a previous reapportionment, the final rule did not account for the change in the number of States and units, as New Jersey production levels met the threshold to separate from the Eastern Region. Due to that oversight, AMS is making the correction. Technical corrections to the regulations would adjust the number of States and units from 30 to 31.

Initial Regulatory Flexibility Act

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), AMS considered the economic effect of this action on small entities and determined that this proposed rule would not have a significant economic impact on a substantial number of small entities. The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly burdened.

Effective November 20, 2019, the Small Business Administration (SBA) [13 CFR 121.201] published an interim final rule (84 FR 64013) that adjusts the monetary-based size standards for inflation. As a result of this rule, the size classification for soybean producers changed from sales of $750,000 or less to sales of $1,000,000 or less. There are an estimated 515,008 soybean producers and an estimated 10,000 first purchasers who collect the assessment, most of whom would be considered small businesses under the criteria established by SBA.

According to USDA's NASS 2017 Census of Agriculture, the number of operations in the United States with soybean production totaled 303,191.[1] The most recent (2017) Census of Agriculture data show that roughly 2 percent of producers with soybean production, or 35,852 operations, have annual receipts of $1,000,000 or more.[2] Therefore, the vast majority of soybean producers, 98 percent, would be considered small businesses with the new SBA guidance. It should be noted that producers are only indirectly impacted by the proposed rule.

The proposed rule imposes no new burden on the industry, as it only adjusts representation on the Board to reflect changes in soybean production. The adjustments are required by the Order and would result in a decrease in Board membership from 78 to 77.

AMS is committed to complying with E-Government Act of 2002 to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

List of Subjects in 7 CFR Part 1220

Administrative practice and procedure, Advertising, Agricultural research, Marketing agreements, Soybeans and soybean products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, AMS proposes to amend 7 CFR part 1220 as follows:

PART 1220—SOYBEAN PROMOTION, RESEARCH, AND CONSUMER INFORMATION

■ 1. The authority citation for 7 CFR part 1220 continues to read as follows:

Authority: 7 U.S.C. 6301–6311 and 7 U.S.C. 7401.

■ 2. In § 1220.201, revise paragraph (a) to read as follows:

§ 1220.201 Membership of Board.

(a) For the purposes of nominating and appointing producers to the Board, the United States shall be divided into 31 geographic units and the number of Board members from each unit, subject to paragraphs (d) and (e) of this section shall be as follows:

State/unit	Number of members
South Dakota	4
Ohio	4
North Dakota	4
Nebraska	4
Missouri	4
Minnesota	4
Iowa	4
Indiana	4
Illinois	4
Wisconsin	3
Tennessee	3
Mississippi	3
Michigan	3
Kentucky	3
Kansas	3

[1] *https://www.nass.usda.gov/AgCensus/index.php.*

[2] *https://quickstats.nass.usda.gov/results/A2ADD567-7CE0-3063-9BAD-CB6C0D073DDA.*

State/unit	Number of members
Arkansas	3
Virginia	2
Pennsylvania	2
North Carolina	2
Maryland	2
Louisiana	2
Alabama	1
Texas	1
South Carolina	1
Oklahoma	1
New York	1
New Jersey	1
Georgia	1
Delaware	1

Unit	Number of members
Eastern Region (Connecticut, Florida, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont, West Virginia, District of Columbia, and Puerto Rico)	1
Western Region (Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming	1

* * * * *

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2021–07721 Filed 4–14–21; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF THE TREASURY

Office of the Secretary

31 CFR Part 1

RIN 1505–AC73

Special Inspector General for Pandemic Recovery Committee—Systems: SIGPR .420—Audit and Evaluations Records; SIGPR .421—Case Management System and Investigative Records; and SIGPR .423—Legal Records; Privacy Act of 1974; Proposed Implementation

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: In accordance with the requirements of the Privacy Act of 1974, as amended, the Department of the Treasury, Departmental Offices (DO), gives notice of a proposed exemption for the following new systems of records maintained by the Special Inspector General for Pandemic Recovery (SIGPR) from certain provisions of the Privacy Act:

SIGPR .420—Audit and Evaluations Records

SIGPR .421—Case Management System and Investigative Records

SIGPR .423—Legal Records

The exemption is intended to comply with the legal prohibitions against the disclosure of certain kinds of information and to protect certain information maintained in this system of records.

DATES: Written comments must be received by May 17, 2021.

ADDRESSES: Written comments on this notice may be submitted electronically through the federal government eRulemaking portal at *http://www.regulations.gov.* Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt, and enables the Department of the Treasury (Treasury) to make the comments available to the public. Please note that comments submitted through *https://www.regulations.gov* will be public and can be viewed by members of the public. Due to COVID–19-related restrictions, Treasury has temporarily suspended its ability to receive public comments by mail.

In general, Treasury will post all comments to *https://www.regulations.gov* without change, including any business or personal information provided, such as names, addresses, email addresses, or telephone numbers. All comments received, including attachments and other supporting material, will be part of the public record and subject to public disclosure. You should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: For questions about this notice and privacy issues, contact: Deputy Assistant Secretary for Privacy, Transparency, and Records at U.S. Department of the Treasury, 1500 Pennsylvania Avenue NW, Washington, DC 20220; telephone: (202) 622–5710.

SUPPLEMENTARY INFORMATION: SIGPR was established by the Coronavirus Aid, Relief, and Economic Security (CARES) Act of 2020. SIGPR has the duty to conduct, supervise, and coordinate audits, evaluations, and investigations of the making, purchase, management, and sale of loans, loan guarantees, and other investments made by the Secretary of the Treasury under programs established by the Secretary, as authorized by Section 4018(c) of the CARES Act, and the management by the Secretary of programs, as authorized by Section 4018(c) of the CARES Act. SIGPR's duties and responsibilities are set forth in Section 4018 of the CARES Act, and in the Inspector General Act of 1978, 5 U.S.C. app. 3. SIGPR plans to create these systems of records to facilitate SIGPR's audits, evaluations, investigations, and other operations to (1) promote economy, efficiency, and effectiveness in the administration of such programs; (2) prevent and detect fraud and abuse in the programs and operations within its jurisdiction; and (3) keep the head of the establishment and the Congress fully informed about problems and deficiencies relating to the administration of such programs and operations and the necessity for and progress of corrective action. Treasury is publishing separately the notice of the new system of records to be maintained by SIGPR.

Under 5 U.S.C. 552a(j)(2) and (k)(2), the head of a federal agency may promulgate rules to exempt a system of

records from certain provisions of 5 U.S.C. 552a if the system of records contains investigatory materials compiled for law enforcement purposes. Pursuant to these provisions, Treasury proposes to exempt the following system of records from 5 U.S.C. 552a(c)(3), (c)(4), (d)(1), (d)(2), (d)(3), (d)(4), (e)(1), (e)(2), (e)(3), (e)(4)(G), (e)(4)(H), (e)(4)(I), (e)(5), (e)(8), (f), and (g) of the Privacy Act:

SIGPR .420—Audit and Evaluations Records

SIGPR .421—Case Management System and Investigative Records

SIGPR .423—Legal Records

The following are the reasons the investigatory materials contained in the above-referenced systems of records maintained by SIGPR may be exempted from various provisions of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2) and (k)(2):

(1) Exempted from 5 U.S.C. 552a(e)(4)(G) and (f)(l) (Agency Requirements and Rules) because release would give individuals an opportunity to learn whether they have been identified as suspects or subjects of investigation. As further described in the following paragraph, access to such knowledge may impair the ability of the Department of the Treasury and SIGPR (the Department/SIGPR) to carry out its respective missions, since individuals could:

(i) Take steps to avoid detection;

(ii) Inform associates that an investigation is in progress;

(iii) Learn the nature of the investigation;

(iv) Learn whether they are suspects or, instead, have been identified as alleged law violators;

(v) Begin, continue, or resume illegal conduct upon learning that they are not identified in the system of records; or

(vi) Destroy evidence needed to prove the violation.

(2) Exempted from 5 U.S.C. 552a(d)(1), (e)(4)(H) and (f)(2), (3) and (5) (Access to Records and Agency Requirements and Rules) because release might compromise the Department's/SIGPR's ability to provide useful tactical and strategic information to law enforcement agencies by:

(i) Permitting access to records contained in the systems of records such that it might provide information concerning the nature of current investigations and enable possible violators to avoid detection or apprehension by:

(A) Allowing the discovery of facts that could form the basis for violators' arrests;

(B) Enabling violators to destroy or alter evidence of alleged criminal conduct that could form the basis for arrest; and

(C) Using knowledge of the status of criminal investigations to delay the commission of a crime, or commit a crime at a location that might not be under surveillance.

(ii) Permitting access to either on-going or closed investigative files might also reveal investigative techniques and procedures, the knowledge of which could enable individuals planning crimes to structure their operations to avoid detection or apprehension.

(iii) Permitting access to investigative files and records also could disclose the identity of confidential sources and informants and the nature of the information supplied, and thereby endanger the physical safety of those sources by exposing them to possible reprisals for having provided the information. In addition, confidential sources and informants might refuse to provide criminal investigators with valuable information if they fear their identities may be revealed through disclosure of their names or the nature of the information they supplied. Loss of access to such sources would seriously impair the Department's/SIGPR's ability to carry out its respective mandate.

(iv) Furthermore, providing access to information contained in the systems of records could reveal the identities of undercover law enforcement officers who compiled information regarding the individual's alleged criminal activities and thereby endanger the physical safety of those undercover officers or their families by exposing them to possible reprisals.

(v) By compromising the law enforcement value of the systems of records for the reasons outlined in paragraph (2), subsections (i) through (iv), permitting access in keeping with these provisions would discourage other law enforcement and regulatory agencies, foreign and domestic, from freely sharing information with the Department/SIGPR and thus would restrict the Department's/SIGPR's access to information necessary to accomplish its respective mission most effectively.

(vi) Finally, the dissemination of certain information that the Department/SIGPR maintains in the systems of records is restricted by law.

(3) Exempted from 5 U.S.C. 552a(d)(2), (3) and (4), (e)(4)(H), and (f)(4) (Access to Records) because these provisions pertain to requesting an amendment or noting a dispute to records that are exempt from access for the reasons set forth in paragraph (2) above.

(4) Exempted from 5 U.S.C. 552a(c)(3) (Accounting for Disclosures) because release of the accounting of disclosures of the records in this system could impair the ability of law enforcement agencies outside the Department/SIGPR from making effective use of information provided by the Department/SIGPR. Making accountings of disclosures available to the subjects of an investigation could alert them to the fact that another agency is conducting an investigation into their alleged criminal activities and could reveal the geographic location of the other agency's investigation, the nature and purpose of that investigation, and the dates on which that investigation was active. Individuals possessing such knowledge could take measures to avoid detection or apprehension by altering their operations, transferring their alleged criminal activities to other geographical areas, or destroying or concealing evidence that would form the basis for arrest. In the case of a delinquent account, such release might enable the subject of the investigation to dissipate assets before levy.

(ii) Moreover, providing accountings to the subjects of investigations would alert them to the fact that the Department/SIGPR has information regarding their alleged criminal activities and could inform them of the general nature of that information. Access to such information could reveal the operations of the Department/SIGPR's information-gathering and analysis systems and permit individuals to take steps to avoid detection or apprehension.

(5) Exempted from 5 U.S.C. 552a(c)(4) (Accounting of Disclosures/Notice of Record Correction or Dispute) because this provision depends on an individual's having access to and an opportunity to request amendment of records that are exempt from access for the reasons set out above, this provision should not apply to the systems of records.

(6) Exempted from 5 U.S.C. 552a(e)(4)(I) (Agency Requirements/Publication of the Categories of Records) because it could compromise the Department/SIGPR's ability to provide useful information to law enforcement agencies, since revealing sources for the information could:

(i) Disclose investigative techniques and procedures;

(ii) Result in threats or reprisals against informants by the subjects of investigations; and

(iii) Cause informants to refuse to give full information to criminal investigators for fear of having their identities as sources disclosed.

(7) Exempted from 5 U.S.C. 552a(e)(1) (Agency Requirements/Maintaining Records) because the term ''maintain'' includes ''collect'' and ''disseminate,'' and application of this provision to the systems of records could impair the Department/SIGPR's ability to collect and disseminate valuable law enforcement information in the following ways:

(i) In many cases, especially in the early stages of an investigation, it may be impossible to immediately determine whether information collected is relevant and necessary, and information that initially appears irrelevant and unnecessary often may, upon further evaluation or upon collation with information developed subsequently, prove particularly relevant to a law enforcement program.

(ii) Not all violations of law discovered by the Department/SIGPR fall within the investigative jurisdiction of the Department or SIGPR. To promote effective law enforcement, the Department/SIGPR may disclose such violations to other law enforcement agencies, including state, local and foreign agencies, that have jurisdiction over the offenses to which the information relates. Otherwise, the Department/SIGPR might be placed in the position of having to ignore information relating to violations of law not within the jurisdiction of the Department or SIGPR when that information comes to the Department/SIGPR's attention during the collation and analysis of information in its respective records.

(8) Exempted from 5 U.S.C. 552a(e)(2) (Agency Requirements/Collection from an Individual) because it could impair the Department's ability to collate, analyze, and disseminate investigative, intelligence, and enforcement information. In addition:

(i) Most information collected about an individual under criminal investigation is obtained from third parties, such as witnesses and informants. It is usually not feasible to rely upon the subject of the investigation as a source for information regarding his or her alleged criminal activities.

(ii) An attempt to obtain information from the subject of a criminal investigation will often alert that individual to the existence of an investigation, thereby affording the individual an opportunity to attempt to conceal his or her alleged criminal activities and thus avoid apprehension.

(iii) In certain instances, the subject of a criminal investigation may assert his or her constitutional right to remain silent and refuse to supply information to criminal investigators upon request.

(iv) During criminal investigations, it is often a matter of sound investigative procedure to obtain information from a variety of sources to verify information already obtained from the subject of a criminal investigation or other sources.

(9) Exempted from 5 U.S.C. 552a(e)(3) (Agency Requirements/Informing Individuals) because it could impair the Department/SIGPR's ability to collect and collate investigative, intelligence, and enforcement data. In addition:

(i) Confidential sources or undercover law enforcement officers often obtain information under circumstances in which it is necessary to keep the true purpose of their actions secret so as not to let the subject of the investigation, or his or her associates, know that a criminal investigation is in progress.

(ii) If it became known that the undercover officer was assisting in a criminal investigation, that officer's physical safety could be endangered through reprisal, and that officer may not be able to continue working on the investigation.

(iii) Individuals often feel inhibited talking to a person representing a criminal law enforcement agency but are willing to talk to a confidential source or undercover officer whom they believe is not involved in law enforcement activities.

(iv) Providing a confidential source of information with written evidence that he or she was a source, as required by this provision, could increase the likelihood that the source of information would be subject to retaliation by the subject of the investigation.

(v) Individuals may be contacted during preliminary information gathering, surveys, or compliance projects concerning the administration of the internal revenue laws before any individual is identified as the subject of an investigation. Informing the individual of the matters required by this provision could impede or compromise subsequent investigations.

(10) Exempted from 5 U.S.C. 552a(e)(5) (Agency Requirements/Record Maintenance). Because the definition of ''maintain'' includes ''collect'' and ''disseminate,'' this provision could hinder the initial collection of any information that might not be determined or determinable, at the moment of collection, to be accurate, relevant, timely, and complete. Similarly, application of this provision could seriously restrict the Department/SIGPR's ability to disseminate information pertaining to a possible violation of law to law enforcement and regulatory agencies. In collecting information during a criminal investigation, it is often impossible or unfeasible to determine accuracy, relevance, timeliness, or completeness prior to collection of the information. In disseminating information to law enforcement and regulatory agencies, it is often impossible to determine accuracy, relevance, timeliness, or completeness prior to dissemination because the Department/SIGPR may not have the expertise with which to make such determinations. Information that may initially appear inaccurate, irrelevant, untimely, or incomplete may, when collated and analyzed with other available information, become more pertinent as an investigation progresses. In addition, application of this provision could seriously impede criminal investigators and intelligence analysts in the exercise of their judgment in reporting results obtained during criminal investigations.

(11) Exempted from 5 U.S.C. 552a(e)(8) (Agency Requirements/Notice) because it could reveal investigative techniques and procedures outlined in those records and to prevent revelation of the existence of an ongoing investigation where there is need to keep the existence of the investigation secret.

(12) Exempted from 5 U.S.C. 552a(g) (Civil Remedies) because, if the civil remedies relate to provisions of 5 U.S.C. 552a from which these rules exempt the systems of records, there should be no civil remedies for failure to comply with provisions from which the Department/SIGPR is exempted. Exemption from this provision will also protect the Department/SIGPR from baseless civil court actions that might hamper its ability to collate, analyze, and disseminate investigative, intelligence, and law enforcement data.

Any information from a system of records for which an exemption is claimed under 5 U.S.C. 552a(j)(2) or 5 U.S.C. 552a(k)(2), which is also included in another system of records, retains the same exempt status such information has in the system of records for which such exemption is claimed.

This proposed rule is not a ''significant regulatory action'' ' under Executive Order 12866.

Pursuant to the requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, it is hereby certified that this rulemaking will not have significant economic impact on a substantial number of small entities. The term ''small entity'' is defined to have the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction'' as defined in the RFA.

The proposed regulation, issued under sections (j)(2) and (k)(2) of the Privacy Act, is to exempt certain information maintained by the Department/SIGPR in the above-referenced systems of records from certain Privacy Act requirements in this system of records by individuals who are United States citizens or aliens lawfully admitted for permanent residence. In as much as the Privacy Act rights are personal and apply only to U.S. citizens or an alien lawfully admitted for permanent residence, small entities, as defined in the RFA, are not provided rights under the Privacy Act and are outside the scope of this regulation.

List of Subjects in 31 CFR Part 1

Courts, Freedom of information, Government employees, Privacy.

Part 1, Subpart C of Title 31 of the Code of Federal Regulations is proposed to be amended as follows:

PART 1—[AMENDED]

■ 1. The authority citation for part 1 continues to read as follows:

Authority: 5 U.S.C. 301 and 31 U.S.C. 321. Subpart A also issued under 5 U.S.C. 552, as amended. Subpart C also issued under 5 U.S.C. 552a, as amended.

■ 2. In § 1.36, amend the tables in paragraphs (c)(1)(ii) and (g)(1)(ii) by adding in alphanumeric order the entries for ''SIGPR .420—Audit and Evaluations Records'', ''SIGPR .421—Case Management System and Investigative Records'' and ''SIGPR .423—Legal Records'' to read as follows:

§ 1.36 Systems exempt in whole or in part from provisions of 5 U.S.C. 522a and this part.

* * * * *

(c) * * *

(1) * * *

(ii) * * *

Number	System name
*	*
SIGPR .420	Audit and Evaluations Records.
SIGPR .421	Case Management System and Investigative Records.
SIGPR .423	Legal Records.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

Number	System name
*	*
SIGPR .420	Audit and Evaluations Records.
SIGPR .421	Case Management System and Investigative Records.
SIGPR .423	Legal Records.

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* * * * *

Ryan Law,

Deputy Assistant Secretary Privacy, Transparency, and Records.

[FR Doc. 2021–05888 Filed 4–14–21; 8:45 am]

BILLING CODE 4810–AK–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2020–0703; FRL–10021–94–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; District of Columbia; Regional Haze State Implementation Plan for the Second Implementation Period and Reasonably Available Control Technology for Major Stationary Sources of Nitrogen Oxides; Technical Amendment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the regional haze state implementation plan (SIP) submitted by the District of Columbia (''the District'' or ''DC'') through the Department of Energy and Environment (DOEE) on November 8, 2019, as satisfying applicable requirements under the Clean Air Act (CAA) and EPA's Regional Haze Rule (RHR) for the program's second implementation period. The District's SIP submission addresses the requirement that states must periodically revise their long-term strategies for making reasonable progress towards the national goal of preventing any future, and remedying any existing, anthropogenic impairment of visibility in mandatory Class I Federal areas, including regional haze. EPA is taking this action pursuant to sections 110 and 169A of the CAA. EPA is also proposing to correct an error in the citations in our final approval of the District's revision to the Reasonably Available Control Technology for Major Stationary Sources of Nitrogen Oxides Rule (''DC NO_X RACT rule'') according to our authority under Section 110(k)(6) of the CAA.

DATES: Written comments must be received on or before May 17, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2020–0703 at *https://www.regulations.gov,* or via email to *talley.david@epa.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Erin Trouba, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2023. Ms. Trouba can also be reached via electronic mail at *trouba.erin@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. What action is EPA proposing?

On November 8, 2019, DC DOEE submitted a revision to its SIP to address regional haze for the second implementation period (''DC DOEE 2019 Regional Haze SIP submission''). DC DOEE made this SIP submission to satisfy the requirements of the CAA's regional haze program pursuant to CAA sections 169A and 169B and 40 CFR 51.308. EPA is proposing to find that the DC DOEE 2019 Regional Haze SIP submission meets the applicable statutory and regulatory requirements and thus proposes to approve the District's submission into its SIP.

EPA is also proposing to correct an error in the citations of the regulatory provisions in our final rule (FRN) and identification of plan of the DC NO_X RACT rule (February 24, 2020, 85 FR 10295) according to our authority to make corrections to prior SIP actions under Section 110(k)(6) of the CAA.

II. Background and Requirements for Regional Haze Plans

A. Regional Haze Background

In the 1977 CAA amendments, Congress created a program for protecting visibility in the nation's mandatory Class I Federal areas, which include certain national parks and wilderness areas.[1] 42 U.S.C. 7491. The CAA establishes as a national goal the ''prevention of any future, and the remedying of any existing, impairment of visibility in mandatory class I Federal areas which impairment results from manmade air pollution.'' 42 U.S.C. 7491(a)(1). The CAA further directs EPA to promulgate regulations to assure reasonable progress toward meeting this national goal. 42 U.S.C. 7491(a)(4). On December 2, 1980, EPA promulgated regulations to address visibility impairment in mandatory Class I Federal areas (hereinafter referred to as ''Class I areas'') that is ''reasonably attributable'' to a single source or small group of sources. 45 FR 80084. These regulations, codified at 40 CFR 51.300 through 51.307, represented the first phase of EPA's efforts to address visibility impairment. In 1990, Congress added section 169B to the CAA to further address visibility impairment, specifically, impairment from regional haze. 42 U.S.C. 7492. EPA promulgated the RHR, codified at 40 CFR 51.308,[2] on July 1, 1999. 64 FR 35714. These regional haze regulations are a central component of EPA's comprehensive visibility protection program for Class I areas.

Regional haze is visibility impairment that is produced by a multitude of sources and activities which are located across a broad geographic area and that emit pollutants that impair visibility. Visibility impairing pollutants include fine and coarse particulate matter (PM) (*e.g.,* sulfates, nitrates, organic carbon, elemental carbon, and soil dust) and their precursors (*e.g.,* sulfur dioxide (SO_2), NO_X, and, in some cases, volatile organic compounds (VOC) and ammonia (NH_3)). Fine particle precursors react in the atmosphere to form fine particulate matter ($PM_{2.5}$), which impairs visibility by scattering and absorbing light. Visibility impairment reduces the perception of clarity and color, as well as visible distance.[3]

To address regional haze visibility impairment, the 1999 RHR established an iterative planning process that requires states in which Class I areas are located and states ''the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility'' in a Class I area to periodically submit SIP revisions to address regional haze visibility impairment. 42 U.S.C. 7491(b)(2); 40 CFR 51.308(b) and (f); see also 64 FR 35768 (July 1, 1999). Under the CAA, each SIP submission must contain ''a long-term (ten to fifteen years) strategy for making reasonable progress toward meeting the national goal,'' 42 U.S.C. 7491(b)(2)(B); the initial round of SIP submissions also had to address the statutory requirement that certain older, larger sources of visibility impairing pollutants install and operate the best available retrofit technology (BART). 42 U.S.C. 7491(b)(2)(A); 40 CFR 51.308(d) and (e). States' first regional haze SIPs were due by December 17, 2007, 40 CFR 51.308(b), with subsequent SIP submissions containing revised long-term strategies originally due July 31, 2018, and every ten years thereafter. 64 FR 35768, July 1, 1999. EPA established in the 1999 RHR that all states either have Class I areas within their borders or ''contain sources whose emissions are reasonably anticipated to contribute to regional haze in a Class I area;'' therefore, all states must submit regional haze SIPs.[4] 64 FR 35721, July 1, 1999.

Much of the focus in the first implementation period of the regional haze program, which ran from 2007 through 2018, was on satisfying states' BART obligations. First implementation period SIPs were additionally required to contain long-term strategies for

[1] Areas statutorily designated as mandatory Class I Federal areas consist of national parks exceeding 6,000 acres, wilderness areas and national memorial parks exceeding 5,000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). There are 156 mandatory Class I areas. The list of areas to which the requirements of the visibility protection program apply is in 40 CFR part 81, subpart D.

[2] In addition to the generally applicable regional haze provisions at 40 CFR 51.308, EPA also promulgated regulations specific to addressing regional haze visibility impairment in Class I areas on the Colorado Plateau at 40 CFR 51.309. The latter regulations are applicable only for specific jurisdictions' regional haze plans submitted no later than December 17, 2007, and thus are not relevant here.

[3] There are several ways to measure the amount of visibility impairment, *i.e.,* haze. One such measurement is the deciview, which is the principle metric used by the RHR. Under many circumstances, a change in one deciview will be perceived by the human eye to be the same on both clear and hazy days. The deciview is unitless. It is proportional to the logarithm of the atmospheric extinction of light, which is the perceived dimming of light due to its being scattered and absorbed as it passes through the atmosphere. Atmospheric light extinction (b^{ext}) is a metric used to for expressing visibility and is measured in inverse megameters ($Mm-1$). The 2019 RHR Guidance offers the flexibility for the use of light extinction in certain cases. Light extinction can be simpler to use in calculations than deciviews, since it is not a logarithmic function. See, *e.g.,* 2019 Guidance at 16, 19. The formula for the deciview is 10 ln (b^{ext})/10 $Mm-1$). 40 CFR 51.301.

[4] In addition to each of the fifty states, EPA also concluded that the Virgin Islands and District of Columbia contain a Class I area and/or contain sources whose emissions are reasonably anticipated to contribute regional haze in a Class I area. See 40 CFR 51.300(b) and (d)(3).

making reasonable progress toward the national visibility goal. The core required elements for the first implementation period SIPs (other than BART) are laid out in 40 CFR 51.308(d). Those provisions required that states containing Class I areas establish reasonable progress goals (RPGs) that are measured in deciviews and reflect the visibility conditions at the end of the implementation period. The first planning period RPGs were required to provide for an improvement in visibility for the most impaired days over the period of the implementation plan and ensure no degradation in visibility for the least impaired days over the same period. In establishing the RPGs for any Class I area in a state, the state was required to consider four statutory factors: The costs of compliance, the time necessary for compliance, the energy and non-air quality environmental impacts of compliance, and the remaining useful life of any potentially affected sources. 42 U.S.C. 7491(g)(1); 40 CFR 51.308(d)(1).

States were also required to calculate baseline (using the five year period of 2000–2004) [5] and natural visibility conditions (*i.e.,* visibility conditions without anthropogenic visibility impairment) for each Class I area, and to calculate the linear rate of progress needed to attain natural visibility conditions, assuming a starting point of baseline visibility conditions in 2004 and ending with natural conditions in 2064. This linear interpolation is known as the uniform rate of progress (URP) and is used as a tracking metric to help states assess the amount of progress they are making towards the national visibility goal over time in each Class I area.[6] 40 CFR 51.308(d)(1)(i)(B) and (d)(2). The 1999 RHR also provided that States must submit long-term strategies that include the ''enforceable emissions limitations, compliance, schedules, and other measures as necessary to achieve the reasonable progress goals,'' *id.* at 40 CFR 51.308(d)(3), and required that, in establishing their long-term strategies, states consult with other states that also contribute to visibility impairment in a Class I area and include all measures necessary to obtain their shares of the emission reductions needed to meet the RPGs. *Id.* at 40 CFR 51.308(d)(3)(i) and (ii). Section 51.308(d) also contains seven additional factors states must consider in formulating their long-term strategies, *id.* at 40 CFR 51.308(d)(3)(v), as well as provisions governing monitoring and other implementation plan requirements, *id.* at 40 CFR 51.308(d)(4). Finally, the 1999 RHR required states to submit periodic progress reports—SIP revisions due every five years that contain information on states' implementation of their regional haze plans and an assessment of whether anything additional is needed to make reasonable progress, see 40 CFR 51.308(g) and (h)—and to consult with the Federal Land Manager(s) [7] (FLMs) responsible for each Class I area according to the requirements in 42 U.S.C. 7491(d) and 40 CFR 51.308(i).

On January 10, 2017, EPA promulgated revisions to the RHR that apply for the second and subsequent implementation periods. 82 FR 3078. The 2017 rule made several changes to the requirements for regional haze SIPs to clarify States' obligations and streamline certain regional haze requirements. The revisions to the regional haze program for the second and subsequent implementation periods focused on the requirement that States' SIPs contain long-term strategies for making reasonable progress towards the national visibility goal. The reasonable progress requirements as revised in the 2017 rule (referred to here as the 2017 RHR Revisions) are codified at 40 CFR 51.308(f). Among other changes relative to the first period requirements, the 2017 RHR Revisions adjusted the deadline for States to submit their second-implementation-period SIPs from July 31, 2018 to July 31, 2021, clarified the order of analysis and the relationship between RPGs and the long-term strategy, and focused on making visibility improvements on the days with the most *anthropogenic* visibility impairment, as opposed to the days with the most visibility impairment overall. EPA also revised requirements of the visibility protection program related to periodic progress reports and FLM consultation. The specific requirements applicable to second implementation period regional haze SIP submissions are addressed in detail below.

EPA provided guidance to the States for their second implementation period SIP submissions in the preamble to the 2017 RHR Revisions as well as in subsequent, stand-alone guidance documents. In August 2019, EPA issued ''Guidance on Regional Haze State Implementation Plans for the Second Implementation Period'' (''2019 Guidance'').[8] Additionally, EPA further clarified the recommended procedures for processing ambient visibility data and optionally adjusting the URP to account for international anthropogenic and prescribed fire impacts in two technical guidance documents: The December 2018 ''Technical Guidance on Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program'' [9] (2018 Visibility Tracking Guidance), and the June 2020 ''Recommendation for the Use of Patched and Substituted Data and Clarification of Data Completeness for Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program'' and associated Technical Addendum.[10]

B. Roles of Agencies in Addressing Regional Haze

Because the air pollutants and pollution affecting visibility in Class I

[5] Additional information on the five-year average baseline calculation requirement in 40 CFR 51.308(f)(1)(i) is contained in: ''Recommendation for the Use of Patched and Substituted Data and Clarification of Data Completeness for Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program.'' EPA Office of Air Quality Planning and Standards, Research Triangle Park (June 3, 2020). *Available at: https://www.epa.gov/visibility/memo-and-technical-addendum-ambient-data-usage-and-completeness-regional-haze-program.*

[6] EPA established the URP framework in the 1999 RHR to provide ''an equitable analytical approach'' to assessing the rate of visibility improvement at Class I areas across the country. The endpoint for the URP analysis was calculated based on the amount of visibility improvement that was anticipated to result from implementation of existing CAA programs over the period from the mid-1990s to approximately 2005. Assuming this rate of progress would continue into the future, EPA determined that natural visibility conditions would be reached in 2064. However, EPA did not establish 2064 as the year by which the national goal *must* be reached. 64 FR 35731–32, July 1, 1999. That is, the URP and the 2064 date are not enforceable targets, but are rather tools that ''allow for analytical comparisons between the rate of progress that would be achieved by the state's chosen set of control measures and the URP.'' 82 FR 3084, January 10, 2017.

[7] EPA's regulations define ''Federal Land Manager'' as ''the Secretary of the department with authority over the Federal Class I area (or the Secretary's designee) or, with respect to Roosevelt-Campobello International Park, the Chairman of the Roosevelt-Campobello International Park Comission.'' 40 CFR 51.301.

[8] Guidance on Regional Haze State Implementation Plans for the Second Implementation Period. *Available at: https://www.epa.gov/visibility/guidance-regional-haze-state-implementation-plans-second-implementation-period* EPA Office of Air Quality Planning and Standards, Research Triangle Park (August 20, 2019).

[9] Technical Guidance on Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program. *Available at: https://www.epa.gov/visibility/technical-guidance-tracking-visibility-progress-second-implementation-period-regional* EPA Office of Air Quality Planning and Standards, Research Triangle Park. (December 20, 2018).

[10] Recommendation for the Use of Patched and Substituted Data and Clarification of Data Completeness for Tracking Visibility Progress for the Second Implementation Period of the Regional Haze Program. *Available at: https://www.epa.gov/visibility/memo-and-technical-addendum-ambient-data-usage-and-completeness-regional-haze-program,* EPA Office of Air Quality Planning and Standards, Research Triangle Park (June 3, 2020).

areas can be transported over long distances, successful implementation of the regional haze program requires long-term, regional coordination among multiple jurisdictions and agencies that have responsibility for Class I areas and the emissions that impact visibility in those areas. In order to address regional haze, states need to develop strategies in coordination with one another, considering the effect of emissions from one jurisdiction on the air quality in another. Five regional planning organizations (RPOs), which include representation from state and tribal governments, EPA, and FLMs, were developed in the lead-up to the first implementation period to address regional haze. RPOs evaluate technical information to better understand how emissions from State and Tribal land impact Class I areas across the country, pursue the development of regional strategies to reduce emissions of particulate matter and other pollutants leading to regional haze, and help states meet the consultation requirements of the RHR.

The Mid-Atlantic/Northeast Visibility Union (MANE–VU), one of the five RPOs described above, is a collaborative effort of state governments, tribal governments, and various Federal agencies established to initiate and coordinate activities associated with the management of regional haze, visibility, and other air quality issues in the Mid-Atlantic and Northeast corridor of the United States. Member states and tribal governments (listed alphabetically) include: Connecticut, Delaware, the District of Columbia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Penobscot Indian Nation, Rhode Island, St. Regis Mohawk Tribe, and Vermont. The non-voting Federal partner members of MANE–VU are EPA, U.S. National Parks Service (NPS), U.S. Fish and Wildlife Service (FWS), and U.S. Forest Service (USFS).

III. Requirements for Regional Haze Plans for the Second Implementation Period [11]

Under the CAA and EPA's regulations, all 50 states, the District of Columbia, and the U.S. Virgin Islands are required to submit regional haze SIPs satisfying the applicable requirements for the second implementation period of the regional haze program by July 31, 2021. Each state's SIP must contain a long-term (ten to fifteen years) strategy for making reasonable progress toward meeting the national goal of remedying any existing and preventing any future anthropogenic visibility impairment in Class I areas. 42 U.S.C. 7491(b)(2)(B). To this end, 40 CFR 51.308(f) lays out the process by which states determine what constitutes their long-term strategies, with the order of the requirements in 40 CFR 51.308(f)(1) through (3) generally mirroring the order of the steps in the reasonable progress analysis [12] and (f)(4) through (6) containing additional, related requirements. Broadly speaking, a state first must identify the Class I areas within the state and determine the Class I areas outside the state in which visibility may be affected by emissions from the state. These are the Class I areas that must be addressed in the state's long-term strategy. See 40 CFR 51.308(f) introductory text and (f)(2). For each Class I area within its borders, a state must then calculate the baseline, current, and natural visibility conditions for that area, as well as the visibility improvement made to date and the URP. See 40 CFR 51.308(f)(1). Each state having a Class I area and/or emissions that may affect visibility in a Class I area must then develop a long-term strategy that includes the enforceable emission limitations, compliance schedules, and other measures that are necessary to make reasonable progress in such areas. Reasonable progress is determined by applying the four factors in CAA section 169A(g)(1) to a set of sources of visibility-impairing pollutants the state has selected to assess for controls for the second implementation period. See 40 CFR 51.308(f)(2). After a state has developed its long-term strategy, including by determining what level of control for visibility-impacting sources represents reasonable progress, it then establishes RPGs for each Class I area within its borders by modeling the visibility impacts of all reasonable progress controls at the end of the second implementation period, *i.e.,* in 2028, as well as the impacts of other requirements of the CAA. The RPGs include reasonable progress controls not only for sources in the state in which the Class I area is located, but also for sources in other states that contribute to visibility impairment in that area. The RPGs are then compared to the baseline visibility conditions and the uniform rate of progress to ensure that progress is being made towards the statutory goal of preventing any future and remedying any existing visibility impairment in Class I areas. *Id.* 40 CFR 51.308(f)(3).

In addition to satisfying the requirements at 40 CFR 51.308(f) related to reasonable progress, the SIP submissions due by July 31, 2021, for the second implementation period must address the requirements in 40 CFR 51.308(g)(1) through (5) pertaining to periodic reports describing progress towards the RPGs, 40 CFR 51.308(f)(5), as well as requirements for FLM consultation that apply to all visibility protection SIPs and SIP revisions. 40 CFR 51.309(i). A state must submit its regional haze SIP and subsequent SIP revisions to EPA according to the requirements applicable to all SIP revisions under the CAA and EPA's regulations. See 42 U.S.C. 7491(b)(2); 7410(a). Upon EPA approval, a SIP is enforceable by the Agency and the public under the CAA. If EPA finds that a state fails to make a required SIP revision, or if EPA finds that a state's SIP is incomplete or if disapproves the SIP, the Agency must promulgate a federal implementation plan (FIP) that satisfies the applicable requirements. 42 U.S.C. 7410(c)(1).

A. Identification of Class I Areas

The SIP revision submission due by July 31, 2021, ''must address regional haze in each mandatory Class I Federal area located within the State and in each mandatory Class I Federal area located outside the State that may be affected by emissions from within the State.'' 40 CFR 51.308(f); see also 40 CFR 51.308(f)(2).[13] Thus, the first step in developing a regional haze SIP is for a state to determine which Class I areas, in addition to those within its borders, ''may be affected'' by emissions from within the state. In the 1999 RHR, EPA determined that all states contribute to visibility impairment in at least one Class I area (64 FR 35720–22, July 1, 1999) and explained that the statute and regulations lay out an ''extremely low triggering threshold'' for determining ''whether States should be required to engage in air quality planning and analysis as a prerequisite to determining the need for control of emissions from sources within their State.'' *Id.* at 35721.

A state must determine which Class I areas must be addressed by its SIP by evaluating the total emissions of

[11] Note that this section provides a narrative description of the RHR. The actual legal requirements against which SIP submissions for the second implementation period are evaluated are those contained in CAA sections 169A and 40 CFR 51.308(f).

[12] EPA explained in the 2017 RHR Revisions that we were adopting new regulatory language in 40 CFR 51.308(f) that, unlike the structure in 40 CFR 51.308(d), ''tracked the actual planning sequence.'' 82 FR 3091 (January 10, 2017).

[13] The RHR uses the phrase ''that may be affected by emissions from the State'' to implement CAA 169A(b)(2)'s requirement that a state ''the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility'' submit a SIP.

visibility impairing pollutants from all sources within the state. While the RHR does not require this assessment to be conducted in any particular manner, EPA's 2019 Guidance provides recommendations for how such an assessment might be accomplished, including by, where appropriate, using the determinations previously made for the first implementation period. 2019 Guidance at 8–9. As explained below, the determination of which Class I areas may be affected by a state's emissions is subject to the requirement in 40 CFR 51.308(f)(2)(iii) to ''document the technical basis, including modeling, monitoring, cost, engineering, and emissions information, on which the State is relying to determine the emission reduction measures that are necessary to make reasonable progress in each mandatory Class I Federal area it affects.''

B. Calculations of Baseline, Current, and Natural Visibility Conditions; Progress to Date; and the Uniform Rate of Progress (URP)

As part of assessing whether a proposed SIP submission for the second implementation period is providing for reasonable progress towards the national visibility goal, the RHR contains requirements in 40 CFR 51.308(f)(1) related to tracking visibility improvement over time. The requirements of this subsection apply only to states having Class I areas within their borders; the required calculations must be made for each such Class I area. EPA's 2018 Visibility Tracking Guidance [14] provides recommendations to assist states in satisfying their obligations under 40 CFR 51.308(f)(1), specifically, in developing information on baseline, current, and natural visibility conditions, and in making optional adjustments to the URP to account for the impacts of international anthropogenic emissions. See 82 FR 3103–05 (January 10, 2017).

The RHR requires tracking of visibility conditions on two sets of days: the clearest and the most impaired days. Visibility conditions for both sets of days are expressed as the average deciview index for the relevant five-year period (the period representing baseline or current visibility conditions). The RHR provides that the relevant sets of days for visibility tracking purposes are the 20% clearest (the 20% of monitored days in a calendar year with the lowest values of the deciview index) and 20% most impaired days (the 20% of monitored days in a calendar year with the highest amounts of anthropogenic visibility impairment).[15] 40 CFR 51.301. A state must calculate visibility conditions for both the 20% clearest and 20% most impaired days for the baseline period of 2000–2004 and the most recent five-year period for which visibility monitoring data are available (representing current visibility conditions). 40 CFR 51.308(f)(1)(i) and (iii). States must also calculate natural visibility conditions for the clearest and most impaired days,[16] by estimating the conditions that would exist on those two sets of days absent anthropogenic visibility impairment. 40 CFR 51.308(f)(1)(ii). Using all these data, states must then calculate, for each Class I area, the amount of progress made since the baseline period (2000–2004) and how much improvement is left to achieve in order to reach natural visibility conditions.

Using the data for the set of most impaired days only, states must plot a line between visibility conditions in the baseline period and natural visibility conditions for each Class I area to determine the URP—the amount of visibility improvement, measured in deciviews, that would need to be achieved during each implementation period in order to achieve natural visibility conditions by the end of 2064. The URP is used in later steps of the reasonable progress analysis for informational purposes and to provide a non-enforceable benchmark against which to assess a Class I area's rate of visibility improvement.[17] Additionally, in the 2017 RHR Revision, EPA provided states the option of proposing to adjust the end-point of the URP to account for impacts of anthropogenic sources outside the United States and/or impacts of certain types of wildland prescribed fires. These adjustments, which must be approved by EPA, are intended to avoid any perception that states should compensate for impacts from international anthropogenic sources and to give states the flexibility to determine that limiting the use of wildland-prescribed fire is not necessary for reasonable progress. 82 FR 3107 n.116 (January 10, 2017).

C. Long-Term Strategy for Regional Haze

The core component of a regional haze SIP submission is a long-term strategy that addresses regional haze in each Class I area within a state's borders and each Class I area that may be affected by emissions from the state. The long-term strategy ''must include the enforceable emissions limitations, compliance schedules, and other measures that are necessary to make reasonable progress, as determined pursuant to 40 CFR 51.308(f)(2)(i) through (iv).'' 40 CFR 51.308(f)(2). The amount of progress that is ''reasonable progress'' is determined by applying the four statutory factors in CAA section 169A(g)(1) in an evaluation of potential control options for sources of visibility impairing pollutants, which is referred to as a ''four-factor'' analysis. The outcome of that analysis is the level of control of emissions that a particular source or group of sources needs to achieve in order to make reasonable progress towards the national visibility goal. The RHR refers to the controls identified pursuant to a four-factor analysis as ''emission reduction measures.'' See, *e.g.,* 40 CFR 51.308(f)(2)(i). Such measures, along with any ''enforceable emissions limitations, compliance schedules, and other measures'' (*i.e.,* any compliance tools) that are necessary to ensure that the level of control identified as ''reasonable progress'' is in fact achieved, become part of a state's long-term strategy. 40 CFR 51.308(f)(2).

Section 51.308(f)(2)(i) provides the requirements for the four-factor analysis. The first step of this analysis entails selecting the sources to be evaluated for emission reduction measures; to this end, the RHR requires states to consider ''major and minor stationary sources or groups of sources, mobile sources, and area sources'' of visibility impairing pollutants to which the four statutory factors will be applied in an analysis of potential controls. 40 CFR 51.308(f)(2)(i). While states have the option to analyze *all* sources, the 2019 Guidance explains that ''an analysis of control measures is not

[14] The 2018 Visibility Tracking Guidance references and relies on parts of the 2003 Tracking Guidance: ''Guidance for Tracking Progress Under the Regional Haze Rule,'' *available at: https://www.epa.gov/visibility/guidance-tracking-progress-under-regional-haze-rule.*

[15] This document also refers to the 20% clearest and 20% most anthropogenically impaired days as the ''clearest'' and ''most impaired'' or ''most anthropogenically impaired'' days, respectively.

[16] The RHR at 40 CFR 51.308(f)(1)(ii) contains an error related to the requirement for calculating two sets of natural conditions values. The rule says ''most impaired days or the clearest days'' where it should say ''most impaired days and clearest days.'' This is an error that was intended to be corrected in the 2017 RHR Revisions but did not get corrected in the final rule language. This is supported by the preamble text at 82 FR 3098, January 10, 2017: ''In the final version of 40 CFR 51.308(f)(1)(ii), an occurrence of ''or'' has been corrected to ''and'' to indicate that natural visibility conditions for both the most impaired days and the clearest days must be based on available monitoring information.''

[17] Being on or below the URP is not a ''safe harbor,'' *i.e.,* achieving the URP does not mean that a Class I area is making ''reasonable progress'' and does not relieve a state from using the four statutory factors to determine what level of control is needed to achieve such progress. See, *e.g.,* 82 FR at 3093, January 10, 2017.

required for every source in each implementation period,'' and that ''[s]electing a set of sources for analysis of control measures in each implementation period is . . . consistent with the Regional Haze Rule, which sets up an iterative planning process and anticipates that a state may not need to analyze control measures for all its sources in a given SIP revision.'' 2019 Guidance at 9. The 2019 Guidance further provides recommendations and considerations for potential approaches to selecting sources for a four-factor analysis based on the fundamental premise that ''[a] state opting to select a set of its sources to analyze must reasonably choose factors [*i.e.,* considerations for source selection] and apply them in a reasonable way given the statutory requirement to make reasonable progress towards natural visibility.'' 2019 Guidance at 10. To this end, 40 CFR 51.308(f)(2)(i) requires that a state's SIP submission include ''a description of the criteria it used to determine which sources or groups of sources it evaluated.'' The technical basis for source selection, which may include methods for quantifying potential visibility impacts such as emissions divided by distance metrics, trajectory analyses, residence time analyses, and/or photochemical modeling, is also subject to 40 CFR 51.308(f)(2)(iii)'s documentation requirement.

Once a state has selected the set of sources (if it has chosen not to analyze all sources of visibility impairment), the next step is to apply the four factors—''the costs of compliance, the time necessary for compliance, and the energy and quality environmental impacts of compliance, and the remaining useful life of any existing source subject to such requirements,'' 42 U.S.C. 7491A(g)(1)—to determine what level of emissions from those sources represents reasonable progress for the second implementation period.[18] EPA has explained that the four-factor analysis is an assessment of potential emission reduction measures (*i.e.,* control options) for sources; ''use of the terms 'compliance' and 'subject to such requirements' in section 169A(g)(1) strongly indicates that Congress intended the relevant determination to be the requirements with which sources would have to comply in order to satisfy the CAA's reasonable progress mandate.'' 82 FR 3091 (January 10, 2017). Thus, for each source it has selected for four-factor analysis,[19] a state must consider a ''meaningful set'' of technically feasible control options for reducing emissions of visibility impairing pollutants. *Id.* at 3088. The 2019 Guidance provides that ''[a] state must reasonably pick and justify the measures that it will consider, recognizing that there is no statutory or regulatory requirement to consider all technically feasible measures or any particular measures. A range of technically feasible measures available to reduce emissions would be one way to justify a reasonable set.'' 2019 Guidance at 29.

After identifying a reasonable set of control options for the sources it has selected, a state then collects information on the four factors with regard to each control option identified; this information will be considered when weighing the factors and selecting the control option that represents reasonable progress. EPA has also explained that, in addition to the four statutory factors, states have flexibility under the CAA and RHR to reasonably consider visibility benefits as an optional fifth factor alongside the four statutory factors.[20] Here, again, the 2019 Guidance provides recommendations for the types of information that can be used to characterize the four factors (with or without visibility), as well as ways in which states might reasonably consider and balance that information to determine which of the potential control options is necessary to make reasonable progress. See 2019 Guidance at 30–36. While states have discretion to reasonably weigh the factors and to determine what level of control is needed, 40 CFR 51.308(f)(2)(i) provides that a state ''must include in its implementation plan a description of . . . how the four factors were taken into consideration in selecting the measure for inclusion in its long-term strategy.'' [21]

As explained above, 40 CFR 51.308(f)(2)(i) requires states to determine the emission reduction measures for sources that are necessary to make reasonable progress by considering the four factors. Section 51.308(f)(2) in turn requires that a state's long-term strategy, which becomes part of its SIP, include ''the enforceable emissions limitations, compliance schedules, and other measures'' that are necessary to ensure that the level of control identified pursuant to the four-factor analysis, *i.e.,* the amount of progress that is ''reasonable progress,'' is achieved. That is, a state must include in its SIP any emission limitations and other compliances measures (*e.g.,* compliance schedules and monitoring, reporting, and recordkeeping requirements) that are needed to ensure that a source in fact achieves and continues to achieve the level of emissions control that resulted from application of the four factors.

As with source selection, the characterization of information on each of the factors is also subject to the documentation requirement in 40 CFR 51.308(f)(2)(iii). The reasonable progress analysis, including source selection, information gathering, characterization of the four statutory factors (and potentially visibility), balancing of the four factors, and selection of the emission reduction measures that represent reasonable progress, is a technically complex exercise, but also a flexible one that provides states with bounded discretion to design and implement approaches appropriate to their circumstances. Given this flexibility, 40 CFR 51.308(f)(2)(iii) plays an important function in requiring a state to document the technical basis for its decision making so that the public and EPA can comprehend and evaluate the information and analysis the state relied upon to determine what emission reduction measures must be in place to make reasonable progress. The technical documentation must include the modeling, monitoring, cost, engineering, and emissions information on which the state relied to determine the measures necessary to make reasonable progress. This documentation requirement can be met through the provision of and reliance on technical analyses developed through a regional planning process, so long as that process and its

[18] The CAA provides that, ''[i]n determining reasonable progress there shall be taken into consideration'' the four statutory factors. 42 U.S.C. 7491(g)(1). However, in addition to four-factor analyses for selected sources, groups of sources, or source categories, a state may also consider additional emission reduction measures for inclusion in its long-term strategy, *e.g.,* from other newly adopted or on-the-books and/or on-the-way rules and measures for sources not explicitly selected for four-factor analysis for the second planning period.

[19] ''Each source'' or ''particular source'' is used here as shorthand. While a source-specific analysis is one way of applying the four factors, neither the statute nor the RHR requires states to evaluate individual sources. Rather, states have ''the flexibility to conduct four-factor analyses for specific sources, groups of sources or even entire source categories, depending on state policy preferences and the specific circumstances of each state.'' 82 FR 3088, January 10, 2017.

[20] See, *e.g.,* Responses to Comments on Protection of Visibility: Amendments to Requirements for State Plans; Proposed Rule (81 FR 26942, May 4, 2016), Docket Number EPA–HQ–OAR–2015–0531, U.S. Environmental Protection Agency at 186; 2019 Guidance at 36–37.

[21] This requirement extends to consideration of visibility as an optional fifth factor; because visibility is not explicitly enumerated as a potential factor in the RHR it is also not explicitly mentioned in 40 CFR 51.308(f)(2)(i).

output has been approved by all state participants.

The four statutory factors (and potentially visibility) are used to determine what emission reduction measures for selected sources must be included in a state's long-term strategy for making reasonable progress. Additionally, the RHR at 40 CFR 51.308(f)(2)(iv) separately provides five additional factors [22] that states must consider in developing their long-term strategies, which we paraphrase: (1) Emission reductions due to ongoing air pollution control programs (2) measures to reduce the impacts of construction activities; (3) source retirement and replacement schedules; (4) basic smoke management practices; and (5) the anticipated net effect on visibility. EPA has explained that a state may satisfy this requirement by considering these additional factors in the process of selecting sources for four-factor analysis, when performing that analysis, or both, and that not every one of the additional factors needs to be considered at the same stage of the process. See 2019 Guidance at 21.

Because the air pollution that causes regional haze crosses state boundaries, 40 CFR 51.308(f)(2)(ii) requires a state to consult with other states that also have emissions that are reasonably anticipated to contribute to visibility impairment in a given Class I area. The purpose of consultation is for each state that impacts visibility in an area to share whatever technical information, analyses, and control determinations may be necessary to develop coordinated emission management strategies. This coordination may be managed through inter- and intra-RPO consultation and the development of regional emissions strategies; additional consultations between states outside of RPO processes may also occur. While there is no requirement that a state include in its long-term strategy the emission reduction measures identified by other states, the RHR does require that a state at least consider such measures for its own sources. 40 CFR 51.308(f)(2). If a state, pursuant to consultation, agrees that certain measures (*e.g.,* a certain emission limitation) are necessary to make reasonable progress at a Class I area, it must include those measures in its SIP. 40 CFR 51.308(f)(2)(ii)(A). However, if a state has been asked to consider or adopt certain emission reduction measures, but ultimately determines those measures are not necessary to make reasonable progress, that state must document in its SIP the actions taken to resolve the disagreement. 40 CFR 51.308(f)(2)(ii)(C). EPA will consider the technical information and explanations presented by the submitting state and the state with which it disagrees when considering whether to approve the state's SIP. *Id.;* 2019 Guidance at 53. Under all circumstances, a state must document in its SIP submission all substantive consultations with other contributing states. 40 CFR 51.308(f)(2)(ii)(C).

D. Reasonable Progress Goals

Reasonable progress goals ''measure the progress that is projected to be achieved by the control measures states have determined are necessary to make reasonable progress based on a four-factor analysis,'' 82 FR at 3091, January 10, 2017; their primary purpose is to assist the public and EPA in assessing the reasonableness of states' long-term strategies for making reasonable progress towards the national visibility goal. See 40 CFR 51.308(f)(3)(iii) through (iv). States in which Class I areas are located must establish two RPGs, both in deciviews—one representing visibility conditions on the clearest days and one representing visibility on the most anthropogenically impaired days—for each such area within their borders. 40 CFR 51.308(f)(3)(i). The two RPGs are intended to reflect the projected impacts, on the two sets of days, of the measures the state with the Class I area, as well as all other contributing states, have included in their long-term strategies for the second implementation period.[23] The RPGs also account for the projected impacts of implementing other CAA requirements, including non-SIP based requirements. For this implementation period, the RPGs are set for 2028. Reasonable progress goals are not enforceable targets, 40 CFR 51.308(f)(3)(iii); rather, they ''provide a way for the states to check the projected outcome of the [long-term strategy] against the goals for visibility improvement.'' 2019 Guidance at 46. While states are not legally obligated to achieve the visibility conditions described in their RPGs, 40 CFR 51.308(f)(3)(i) requires that ''[t]he long-term strategy and the reasonable progress goals must provide for an improvement in visibility for the most impaired days since the baseline period and ensure no degradation in visibility for the clearest days since the baseline period.'' Thus, states are required to have emission reduction measures in their long-term strategies that are projected to achieve visibility on the most impaired days that is better than the baseline period, and shows no degradation on the clearest days compared to the clearest days from the baseline period. The baseline period for the purpose of this comparison is the baseline visibility condition—the annual average visibility condition for the period 2000–2004. See 40 CFR 51.308(f)(1)(i), 82 FR 3097–98 (January 10, 2017).

So that RPGs may also serve as a metric for assessing the amount of progress a state is making towards the national visibility goal, the RHR requires states with Class I areas to compare the 2028 RPG for the most impaired days to the corresponding point on the URP line (representing visibility conditions in 2028 if visibility were to improve at a linear rate from conditions in the baseline period of 2000–2004 to natural visibility conditions in 2064). If the most impaired days RPG in 2028 is above the URP (*i.e.,* if visibility conditions are improving more slowly than the rate described by the URP), each contributing state must demonstrate, based on the four-factor analysis required under 40 CFR 51.308(f)(2)(i), that no additional emission reduction measures would be reasonable to include in its long-term strategy. 40 CFR 51.308(f)(3)(ii). To this end, 40 CFR 51.308(f)(3)(ii) requires that each state contributing to visibility impairment in a Class I area that is projected to improve more slowly than the URP provide ''a robust demonstration, including documenting the criteria used to determine which sources or groups [of] sources were evaluated and how the four factors required by paragraph (f)(2)(i) were taken into consideration in selecting the measures for inclusion in its long-term strategy.'' The 2019 Guidance provides suggestions about how such a ''robust demonstration'' might be conducted. See 2019 Guidance at 50–51.

The 2017 RHR and 2019 Guidance also explain that projecting an RPG that is on or below the URP based on only on-the-books and/or on-the-way control

[22] The five additional factors for consideration in 40 CFR 51.308(f)(2)(iv) are distinct from the four factors listed in CAA section 169A(g)(1) and 40 CFR 51.308(f)(2)(i) that states must consider and apply to sources in determining reasonable progress.

[23] RPGs are intended to reflect, among other things, the projected impacts of the measures the states include in their long-term strategies. However, due to the timing of multiple state analyses, determination of the final set of state long-term strategies, and other on-going emissions changes, a particular states' RPGs may not reflect all control measures and emissions reductions that are expected to occur by the end of the implementation period. The statute and rule address this practical challenge by requiring subsequent SIP submittals (every ten years), and periodic progress reports (due five years after each regional haze SIP).

measures (*i.e.,* control measures already required or anticipated before the four-factor analysis is conducted) is not a ''safe harbor'' from the CAA's and RHR's requirement that all states must conduct a four-factor analysis to determine what emission reduction measures constitute reasonable progress. See 82 FR 3078 at 3093, 3099–3100, January 10, 2017; 2019 Guidance at 22.

E. Monitoring Strategy and Other Implementation Plan Requirements

Section 51.308(f)(6) requires states to have certain strategies and elements in place for assessing and reporting on visibility. Individual requirements under this subsection apply either to states with Class I areas within their borders, states with no Class I areas but that are reasonably anticipated to cause or contribute to visibility impairment in any Class I area, or both. A state with Class I areas within its borders must submit with its SIP revision a monitoring strategy for measuring, characterizing, and reporting regional haze visibility impairment that is representative of all Class I areas within the state. SIP revisions for such states must also provide for the establishment of any additional monitoring sites or equipment needed to assess visibility conditions in Class I areas, as well as reporting of all visibility monitoring data to EPA at least annually. Compliance with the monitoring strategy requirement may be met through a state's participation in the Interagency Monitoring of Protected Visual Environments (IMPROVE) monitoring network, which may be used to measure visibility impairment caused by air pollution at the 156 Class I areas covered by the visibility program. 40 CFR 51.308(f)(6) introductory text and (f)(6)(i) and (iv). The IMPROVE monitor data is used to determine the 20 percent most anthropogenically impaired and 20 percent clearest sets of days every year at each Class I area and tracks visibility impairment over time.

All states' SIPs must provide for procedures by which monitoring data and other information are used to determine the contribution of emissions from within the state to regional haze visibility impairment in affected Class I areas. 40 CFR 51.308(f)(6)(ii) and (iii). Section 51.308(f)(6)(v) further requires that all states' SIPs provide for a statewide inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment in any Class I area; the inventory must include emissions for the most recent year for which data are available and estimates of future projected emissions. States must also include commitments to update their inventories periodically. The inventories themselves do not need to be included as elements in the SIP and are not subject to EPA review as part of the Agency's evaluation of a SIP revision.[24] All states' SIPs must also provide for any other elements, including reporting, recordkeeping, and other measures, that are necessary for states to assess and report on visibility. 40 CFR 51.308(f)(6)(vi). Per the 2019 Guidance, a state may note in its regional haze SIP that its compliance with the Air Emissions Reporting Rule (AERR) in 40 CFR part 51, subpart A, satisfies the requirement to provide for an emissions inventory for the most recent year for which data are available. To satisfy the requirement to provide estimates of future projected emissions, a state may explain in its SIP how projected emissions were developed for use in establishing RPGs for its own and nearby Class I areas.[25]

Separate from the requirements related to monitoring for regional haze purposes under 40 CFR 51.308(f)(6), the RHR also contains a requirement at 40 CFR 51.308(f)(4) related to any additional monitoring that may be needed to address visibility impairment in Class I areas from a single source or a small group of sources. This is called ''reasonably attributable visibility impairment.'' [26] Under this provision, if EPA or the FLM of an affected Class I area has advised a state that additional monitoring is needed to assess reasonably attributable visibility impairment, the state must include in its SIP revision for the second implementation period an appropriate strategy for evaluating such impairment.

F. Requirements for Periodic Reports Describing Progress Towards the Reasonable Progress Goals

Section 51.308(f)(5) requires a state's regional haze SIP revision to address the requirements of 40 CFR 51.308(g)(1) through (5) so that the plan revision due in 2021 will serve also as a progress report addressing the period since submission of the progress report for the first implementation period. The regional haze progress report requirement is designed to inform the public and EPA about a state's implementation of its existing long-term strategy and whether such implementation is in fact resulting in the expected visibility improvement. See 81 FR 26942, 26950 (May 4, 2016), 82 FR 3119, January 10, 2017. To this end, every state's SIP revision for the second implementation period is required to describe the status of implementation of all measures included in the state's long-term strategy, including BART and reasonable progress emission reduction measures from the first implementation period, and the resulting emissions reductions. 40 CFR 51.308(g)(1) and (2).

A core component of the progress report requirements is an assessment of changes in visibility conditions on the clearest and most impaired days. Section 51.308(g)(3) requires states with Class I areas within their borders to first determine current visibility conditions for each area, 40 CFR 51.308(g)(3)(i), and then to calculate the difference between those current conditions and baseline (2000–2004) visibility conditions in order to assess progress made to date. See 40 CFR 51.308(g)(3)(ii). For the purposes of 40 CFR 51.308(f)(5) and (g)(3)(iii) provides that the relevant period for assessing changes in visibility is the period since the most recent progress report. EPA interprets this period as starting from the period that represented ''current visibility conditions'' in the first implementation period progress report. Since different states submitted their first implementation period progress reports at different times, the period reflecting ''current visibility conditions'' referenced in each state's progress report will vary.

Similarly, the relevant period for the purpose of 40 CFR 51.308(g)(4)'s analysis of emissions of visibility impairing pollutants starts with the period that represented ''current visibility conditions'' in the progress report for the first implementation period and runs through ''current conditions'' for the second implementation period. This provision requires an analysis tracking the change in emissions of pollutants contributing to visibility impairment from all sources and activities within the state; changes should be identified by (*i.e.,* attributed to) type of source(s) or activity(ies). Section 51.308(g)(5) also addresses changes in emissions since the period addressed by the previous progress report and requires states' SIP revisions to include an assessment of any significant changes in anthropogenic emissions within or outside the state. This assessment must include an explanation of whether these changes in emissions were anticipated and whether

[24] See section ''Step 8: Additional requirements for regional haze SIPs'' in 2019 Regional Haze Guidance at 55.

[25] *Id.*

[26] EPA's visibility protection regulations define ''reasonably attributable visibility impairment'' as ''visibility impairment that is caused by the emission of air pollutants from one, or a small number of sources.'' 40 CFR 51.301.

they have limited or impeded progress in reducing emissions and improving visibility relative to what the state projected based on its long-term strategy for the first implementation period.

G. Requirements for State and Federal Land Manager Coordination

Clean Air Act section 169A(d) requires that before a state holds a public hearing on a proposed regional haze SIP revision, it must consult with the appropriate FLM or FLMs; pursuant to that consultation, the state must include a summary of the FLMs' conclusions and recommendations in the notification to the public. Consistent with this statutory requirement, the RHR also requires that states ''provide the [FLM] with an opportunity for consultation, in person and at a point early enough in the State's policy analyses of its long-term strategy emission reduction obligation so that information and recommendations provided by the [FLM] can meaningfully inform the State's decisions on the long-term strategy.'' 40 CFR 51.308(i)(2). Consultation that occurs 120 days prior to any public hearing or public comment opportunity will be deemed ''early enough,'' but the RHR provides that in any event the opportunity for consultation must be provided at least 60 days before a public hearing or comment opportunity. This consultation must include the opportunity for the FLMs to discuss their assessment of visibility impairment in any Class I area and their recommendations on the development and implementation of strategies to address such impairment. 40 CFR 51.308(i)(2). In order for EPA to evaluate whether FLM consultation meeting the requirements of the RHR has occurred, the SIP submission should include documentation of the timing and content of such consultation. The SIP revision submitted to EPA must also describe how the state addressed any comments provided by the FLMs. 40 CFR 51.308(i)(3). Finally, a SIP revision must provide procedures for continuing consultation between the state and FLMs regarding the state's visibility protection program, including development and review of SIP revisions, five-year progress reports, and the implementation of other programs having the potential to contribute to impairment of visibility in Class I areas. 40 CFR 51.308(i)(4).

IV. EPA's Evaluation of the District's Regional Haze Submission for the Second Implementation Period

A. Background on the District's First Implementation Period SIP Submission

The District submitted its regional haze SIP for the first implementation period to EPA on October 27, 2011. EPA published a final rule fully approving the first DC regional haze SIP submission on February 2, 2012 (77 FR 5191). The requirements for regional haze SIPs for the first implementation period are contained in 40 CFR 51.308(d) and (e). 40 CFR 51.308(b). The District has no Class I areas within its borders. In the first implementation period, MANE–VU used two criteria to determine whether certain SO_2 emissions from individual jurisdictions within the region affected visibility in any Class I areas: Contribution of greater than 0.1 microgram per cubic meter ($\mu g/m^3$) or two percent of sulfate emission contribution. 77 FR 70929, 70935 (November 16, 2011). The District relied on MANE–VU contribution assessment modeling to assert that emissions from the District did not meet either of these criteria. Regardless, EPA explained that ''the District . . . is responsible for developing a regional haze SIP that describes its long-term emission strategy, its role in the consultation processes, and how the SIP meets the other requirements in EPA's regional haze regulations.'' *Id.* Finding the District's SIP submission met the applicable requirements of 40 CFR 51.308(d) and (e), EPA approved its plan for the first implementation period. Pursuant to 40 CFR 51.308(g), the District was also responsible for submitting a five-year progress report as a SIP revision for the first implementation period, which it did on March 2, 2016. EPA approved the progress report into the DC SIP on August 10, 2017 (82 FR 37305).

B. The District's Second Implementation Period SIP Submission and EPA Evaluation

In accordance with CAA sections 169A and the RHR at 40 CFR 51.308(f), on November 8, 2019, DC DOEE submitted a revision to the DC SIP to address the jurisdiction's regional haze obligations for the second implementation period, which runs through 2028. The District made its 2019 Regional Haze SIP submission available for public comment on August 30, 2019 and held a hearing on September 30, 2019. No public comments were received.

The following sections describe the District's SIP submission, including the analyses conducted by MANE–VU and the District's determinations based on those analyses, the District's assessment of progress made since the first implementation period in reducing emissions of visibility impairing pollutants, and the visibility improvement progress at nearby Class I areas. This document also contains EPA's evaluation of the District's submission against the requirements of the CAA and RHR for the second implementation period of the regional haze program.

C. Identification of Class I Areas

Section 169(A)(b)(2) of the CAA requires each state in which any Class I area is located or ''the emissions from which may reasonably be anticipated to cause or contribute to any impairment of visibility'' in a Class I area to have a plan for making reasonable progress toward the national visibility goal. The RHR incorporates this statutory requirement at 40 CFR 51.308(f) introductory text, which provides that each state's plan ''must address regional haze in each mandatory Class I Federal area located within the State and in each mandatory Class I Federal area located outside the State that may be affected by emissions from within the State,'' and (f)(2), which requires each state's plan to include a long-term strategy that addresses regional haze in such Class I areas.

EPA explained in the 1999 RHR preamble that the CAA section 169A(b)(2) requirement that states submit SIPs to address visibility impairment establishes ''an 'extremely low triggering threshold' in determining which States should submit SIPs for regional haze.'' 64 FR 35721, July 1, 1999. In concluding that each of the contiguous 48 states and the District of Columbia meet this threshold,[27] EPA relied on ''a large body of evidence demonstrat[ing] that long-range transport of fine PM contributes to regional haze,'' *id.,* including modeling studies that ''preliminarily demonstrated that each State not having a Class I area had emissions contributing to impairment in at least one downwind Class I area.'' *Id.* at 35722. In addition to the technical evidence supporting a conclusion that each state contributes to *existing*

[27] EPA determined that ''there is more than sufficient evidence to support our conclusion that emissions from each of the 48 contiguous states and the District of Columba may reasonably be anticipated to cause or contribute to visibility impairment in a Class I area.'' 64 FR 35721, July 1, 1999. Hawaii, Alaska, and the U.S. Virgin Islands must also submit regional haze SIPs because they contain Class I areas.

visibility impairment, EPA also explained that the second half of the national visibility goal—preventing *future* visibility impairment—requires having a framework in place to address future growth in visibility-impairing emissions and makes it inappropriate to ''establish criteria for excluding States or geographic areas from consideration as potential contributors to regional haze visibility impairment.'' *Id.* at 35721. Thus, EPA concluded that the agency's ''statutory authority and the scientific evidence are sufficient to require all States to develop regional haze SIPs to ensure the prevention of any future impairment of visibility, and to conduct further analyses to determine whether additional control measures are needed to ensure reasonable progress in remedying existing impairment in downwind Class I areas.'' *Id.* at 35722. EPA's 2017 revisions to the RHR did not disturb this conclusion. See 82 FR 3094, January 10, 2017.

For the second implementation period, MANE–VU performed technical analyses to help inform source and state-level contributions to visibility impairment and the need for interstate consultation.[28] MANE–VU used the results of these analyses to determine which states' emissions ''have a high likelihood of affecting visibility in MANE–VU's Class I areas.'' [29] The MANE–VU analyses used a combination of data analysis techniques, including emissions data, distance from Class I areas, wind trajectories, and CALPUFF dispersion modeling. Many of the analyses focused only on SO_2 emissions and resultant particulate sulfate contributions to visibility impairment, while others also incorporated NO_X emissions to estimate particulate nitrate contributions.

One MANE–VU analysis used for contribution assessment was CALPUFF air dispersion modeling. The CALPUFF model simulated sulfate and nitrate formation and transport in MANE–VU and nearby regions from large electric generating units (EGU) point sources and other large industrial and institutional sources in the eastern and central United States. The CALPUFF modeling run included sources selected using emissions divided by distance, or ''Q/d'' analysis. The CALPUFF modeling summary report included the top 10 most impacting EGUs and the top 5 most impacting industrial sources for each Class I area and compiled those results into a ranked list of the most impacting EGUs and industrial sources at MANE–VU Class I areas.[30] Due to a lack of large EGUs or industrial sources, no District emissions were included in the MANE–VU CALPUFF modeling.[31]

The other MANE–VU analysis used a meteorologically weighted Q/d calculation.[32] The variable ''Q'' is the quantity of cumulative SO_2 emissions from a source or a state, which is divided by the variable ''d,'' which is the distance of the source or state to the IMPROVE monitor receptor at a Class I area. The result is then multiplied by a constant (C_i), which is determined based on the prevailing wind patterns. MANE–VU selected a meteorologically weighted Q/d analysis as an inexpensive initial screening tool that could easily be repeated to determine which states, sectors, or sources have a larger relative impact and warrant further analysis. MANE–VU's analysis estimated the District's maximum sulfate contribution at 0.13% at any Class I area based on the maximum daily impact. The largest impacts from District SO_2 emissions were to Brigantine Wilderness and Shenandoah National Park. The MANE–VU Q/d analysis was further extended to account for nitrate contributions from NO_X emissions. Nitrate impacts were not originally estimated using Q/d, but MANE–VU wanted to include an approximation of nitrate impacts from area and mobile sources. MANE–VU developed a ratio of nitrate to sulfate impacts based on the previously described CALPUFF modeling and applied those to the sulfate Q/d results. Several states, including the District, did not have CALPUFF nitrate to sulfate ratio results because there were no point sources modeled with CALPUFF. For the District, MANE–VU developed a surrogate ratio from the Maryland CALPUFF results.

In order to develop a final set of contribution estimates, MANE–VU weighted the results from both the Q/d and CALPUFF analyses. However, only Q/d results were used for the District, since there were no CALPUFF results for the District. The MANE–VU mass-weighted sulfate and nitrate contribution results were reported for the MANE–VU Class I areas (the Q/d summary report included results for several non-MANE–VU areas as well). The largest District mass-weighted sulfate and nitrate contribution to any Class I area was 0.2% to Brigantine Wilderness. Based on the results of the MANE–VU screening analyses, the District concludes in its regional haze submission that it is ''not 'reasonably anticipated to contribute to visibility impairment' in any Class I Federal area.'' [33]

As explained above, EPA concluded in the 1999 RHR that ''all [s]tates [including the District of Columbia] contain sources whose emissions are reasonably anticipated to contribute to regional haze in a Class I area,'' 64 FR 35721, July 1, 1999 and this determination was not changed in the 2017 RHR. Critically, the statute and regulation both require that the cause-or-contribute assessment consider all emissions of visibility-impairing pollutants from a state, as opposed to emissions of a particular pollutant or emissions from a certain set of sources. Consistent with these requirements, the 2019 Guidance makes it clear that ''all types of anthropogenic sources are to be included in the determination'' of whether a state's emissions are reasonably anticipated to result in any visibility impairment. 2019 Guidance at 8.

The screening analyses on which MANE–VU relied are useful for certain purposes. MANE–VU used the technical analysis information to rank the largest contributing states to sulfate and nitrate impairment in five Class I areas within MANE–VU states and three additional, nearby Class I areas.[34] The rankings were used to determine upwind states that were deemed important to include in state-to-state consultation (based on an identified impact screening threshold), and large individual source impacts were used to target MANE–VU control analysis ''Asks'' of states and sources both within and upwind of MANE–VU.[35] EPA finds the nature of

[28] The technical analysis performed by MANE–VU, including the contribution assessment methodologies for MANE–VU Class I areas, is summarized in appendix 1 of the DC DOEE 2019 Regional Haze SIP submission, ''Selection of States for MANE–VU Regional Haze Consultation (2018).''

[29] *Id.*

[30] See Tables 34 and 35 of appendix 4 of the DC DOEE 2019 Regional Haze SIP submission, ''2016 MANE–VU Source Contribution Modeling Report—CALPUFF Modeling of Large Electrical Generating Units and Industrial Sources (MANE–VU, April 2017).''

[31] See appendix 4 of the DC DOEE 2019 Regional Haze SIP submission.

[32] The methodology used by MANE–VU for the meteorological weighted Q/d analysis can be found in appendix 3 of the DC DOEE 2019 Regional Haze SIP submission, ''MANE–VU Updated Q/d*C Contribution Assessment.''

[33] Section 2.4.3 of the DC DOEE 2019 Regional Haze SIP submission at 9.

[34] The Class I areas analyzed were Acadia National Park in Maine, Brigantine Wilderness in New Jersey, Great Gulf Wilderness in New Hampshire, Lye Brook Wilderness in Vermont, Moosehorn Wilderness in Maine, Shenandoah National Park in Virginia, James River Face Wilderness in Virginia, and Dolly Sods/Otter Creek Wildernesses in West Virginia.

[35] The MANE–VU consultation report (Appendix 7 of the DC DOEE 2019 Regional Haze SIP submission) explains that ''[t]he objective of this technical work was to identify states and sources from which MANE–VU will pursue further

the analyses appropriate to make those types of conclusions. The District has participated in the MANE–VU visibility analysis and has provided information in its SIP submission on the magnitude of visibility impacts from certain District emissions on nearby Class I areas. However, the analyses did not account for all emissions and all components of visibility impairment (*e.g.* primary PM emissions, and impairment from fine PM, elemental carbon, and organic carbon). In addition, a Q/d analysis with a relatively simplistic accounting for wind trajectories and CALPUFF applied to major industrial sources of SO_2 and NO_X are not scientifically rigorous tools capable of ruling out a contribution to visibility impairment from *all* emissions in a state. This is particularly true for the District since the MANE–VU CALPUFF modeling did not include any District sources and because the nitrate impacts used in the Q/d analysis were derived from another state's ratio of nitrate to sulfate impacts. EPA does agree that the contribution to visibility impairment from District emissions at all nearby Class I areas is relatively small, and in fact may be amongst the smallest impacts to visibility impairment from the MANE–VU states. However, based on the information presented in the District's submission, there is not sufficient evidence for EPA to either agree or disagree with the conclusion that emissions from the District are not reasonably anticipated to cause or contribute to any impairment of visibility at any Class I area.

Regardless, the District took part in the emission control strategy consultation process as a member of MANE–VU. As part of that process, MANE–VU developed a set of emissions reduction measures identified as being necessary to make reasonable progress in the five MANE–VU Class I areas. This strategy consists of six Asks for states within MANE–VU and five Asks for states outside the region that were found to impact visibility at Class I areas within MANE–VU.[36] The District's submission discusses each of the Asks and explains why or why not each is applicable and how it has complied with the relevant components of the emissions control strategy MANE–VU has laid out for its states. As discussed in further detail below, EPA is proposing to find that the District has submitted a regional haze plan that meets the requirements of 40 CFR 51.308(f)(2) related to the development of a long-term strategy for the second implementation period.

D. Calculations of Baseline, Current, and Natural Visibility Conditions; Progress to Date; and the URP

Section 51.308(f)(1) requires states to determine the following for each mandatory Class I Federal area located within the State: Baseline visibility conditions for the most impaired and clearest days, natural visibility conditions for the most impaired and clearest days, progress to date for the most impaired and clearest days, the differences between current visibility condition and natural visibility condition, and the uniform rate of progress. This section also provides the option for states to propose adjustments to the URP line to account for the impacts from anthropogenic sources outside the United States and the impacts from wildland prescribed fires that were conducted for certain, specified objectives. 40 CFR 51.308(f)(1)(vi)(B). Because the District does not have any Class I areas within its borders, it is not required to calculate baseline, current, and natural visibility conditions, or to calculate a URP line.[37]

E. Long-Term Strategy for Regional Haze

Each state having a Class I area within its borders or emissions that may affect visibility in a Class I area must develop a long-term strategy for making reasonable progress towards the national visibility goal. CAA 169A(b)(2)(B). As explained in Section II.A. of this document, the long-term strategy must include the enforceable emission limitations, compliance schedules, and other measures that are necessary to make reasonable progress, as determined pursuant to 40 CFR 51.308(f)(2)(i) through (iv). 40 CFR 51.308(f)(2). In determining the emission reduction measures necessary to make reasonable progress, the state must consider the costs of compliance, time necessary for compliance, energy and non-air quality environmental impacts of compliance, and the remaining useful life of any existing source. 40 CFR 51.308(f)(2)(i). As part of this analysis, the state must describe the criteria used to determine which sources or group of sources were evaluated (*i.e.,* subjected to four-factor analysis) for the second implementation period and how the four factors were taken into consideration in selecting the measures for inclusion in the long-term strategy. 40 CFR 51.308(f)(2)(iii). The long-term strategy for making reasonable progress also encompasses any other emission reduction measures a state chooses to include in its overall strategy to address visibility impairment, *e.g.,* newly adopted or on-the-books/on-the-way measures identified pursuant to the five additional factors in 40 CFR 51.308(f)(2)(iv).

1. The District's Response to the Six MANE–VU Asks

This section of the document summarizes how the District's SIP submission addressed the requirements of 40 CFR 51.308(f)(2)(i); specifically, it describes MANE–VU's development of the six Asks and how the District addressed each. EPA's evaluation of the District's SIP revision with regard to the same is contained in the following section, Section IV.E.2. of this document.

States may rely on technical information developed by the RPOs of which they are members to select sources for four-factor analysis and to conduct that analysis, as well as to satisfy the documentation requirements under 40 CFR 51.308(f). Where an RPO has performed source selection and/or four-factor analyses (or considered the five additional factors in 40 CFR 51.308(f)(2)(iv)) for its member states, those states may rely on the RPOS's analyses for the purpose of satisfying the requirements of 40 CFR 51.308(f)(2)(i) so long as the states have a reasonable basis to do so and all state participants in the RPO process have approved the technical analyses. States may also satisfy the requirement of 40 CFR 51.308(f)(2)(ii) to engage in interstate consultation with other states that have emissions that are reasonably anticipated to contribute to visibility impairment in a given Class I area under the auspices of intra- and inter-RPO engagement.

The District is a member of the MANE–VU RPO and participated in the RPO's regional approach to developing a strategy for making reasonable progress towards the national visibility goal in the MANE–VU Class I areas. MANE–VU's strategy includes a combination of (1) measures for certain source sectors and groups of sectors that the RPO determined were reasonable for

analysis. This screening was intended to identify which states to invite to consultation, not a definitive list of which states are contributing.''

[36] See appendix 8 of the DC DOEE 2019 Regional Haze SIP submission, ''Statement of the Mid-Atlantic/Northeast Visibility Union (MANE–VU) Concerning a Course of Action within MANE–VU toward Assuring Reasonable Progress for the Second Regional Haze Implementation Period (2018–2028), (August 2017).''

[37] While the District noted that it was not required to comply with 40 CFR 51.308(f)(1), elsewhere in its SIP submission (section 2.22) it included visibility metric graphs of nearby Class I areas, which were taken from appendix 13, ''Mid-Atlantic/Northeast U.S. Visibility Data 2004–2017 (2nd RH SIP Metrics) (MANE–VU, December 2018).''

states to pursue, and (2) a request for member states to conduct four-factor analyses for individual sources that it identified as contributing to visibility impairment. MANE–VU refers to each of the components of its overall strategy as an Ask of its member states. On August 25, 2017, the Executive Director of MANE–VU, on behalf of the MANE–VU states and tribal nations, signed a statement that identifies six emission reduction measures that comprise the Asks for the second implementation period.[38] The Asks were ''designed to identify reasonable emission reduction strategies that must be addressed by the states and tribal nations of MANE–VU through their regional haze SIP updates.'' [39] The Statement explains that ''[i]f any State cannot agree with or complete a Class I State's Asks, the State must describe the actions taken to resolve the disagreement in the Regional Haze SIP.'' [40]

MANE–VU's recommendations as to the appropriate control measures were based on technical analyses documented in the RPO's reports and included as appendices to or referenced in the District's regional haze SIP submission. One of the initial steps of MANE–VU's technical analysis was to determine which visibility-impairing pollutants should be the focus of its efforts for the second implementation period. In the first implementation period, MANE–VU determined that sulfates were the most significant visibility impairing pollutant at the region's Class I areas. To determine the impact of certain pollutants on visibility at Class I areas for the purpose of second implementation period planning, MANE–VU conducted an analysis comparing the pollutant contribution on the clearest and most impaired days in the baseline period (2000–2004) to the most recent period (2012–2016) [41] at MANE–VU and nearby Class I areas. MANE–VU found that while SO_2 emissions were decreasing and visibility was improving, sulfates still made up the most significant contribution to visibility impairment at MANE–VU and nearby Class I areas. According to the analysis, NO_X emissions have begun to play a more significant role in visibility impacts in recent years, especially at Brigantine Wilderness Area. The District included this analysis in its submission.[42]

To support development of the Asks, MANE–VU gathered information on each of the four factors for six source sectors it determined ''had emissions that were reasonabl[y] anticipated to contribute to visibility degradation in MANE–VU:'' Electric generating units (EGUs), industrial/commercial/institutional boilers (ICI boilers), cement kilns, heating oil, residential wood combustion, and outdoor wood combustion.[43] MANE–VU also collected data on individual sources within the EGU, ICI boiler, and cement kiln sectors.[44] Information for the six sectors included explanations of technically feasible control options for SO_2 or NO_X, illustrative cost-effectiveness estimates for a range of model units and control options, sector-wide cost considerations, potential time frames for compliance with control options, potential energy and non-air-quality environmental impacts of certain control options, and how the remaining useful lives of sources might be considered in a control analysis.[45] Source-specific data included SO_2 emissions [46] and existing controls [47] for certain existing EGUs, ICI boilers, and cement kilns. MANE–VU had this information on the four factors as well as the analyses developed by the RPO's Technical Support Committee before it when it determined the specific emission reduction measures that are reasonable for certain sources within two of the sectors it had examined—EGUs and ICI boilers.

MANE–VU Ask 1 is ''ensuring the most effective use of control technologies on a year-round basis'' at EGUs with a nameplate capacity larger than or equal to 25 megawatts (MW) with already installed NO_X and/or SO_2 controls.[48] In its submission, the District explained that it has no coal-fired EGUs with a nameplate capacity greater than 25 MW and that it is currently meeting Ask 1.

MANE–VU Ask 2 consists of a request that states ''perform a four-factor analysis for reasonable installation or upgrade to emissions controls'' for specified sources. MANE–VU developed its Ask 2 list of sources for analysis by performing modeling and identifying facilities with the potential for 3.0 inverse megameters (Mm^{-1}) or greater impacts on visibility at any Class I area in the MANE–VU region. The District explained that it has no facilities that were modeled by MANE–VU to impact visibility at any Class I area by 3.0 Mm^{-1} or more and concluded that it is currently meeting Ask 2.

Ask 3 is for each MANE–VU state to pursue an ultra low-sulfur fuel oil standard if it has not already done so in the first implementation period. The Ask includes percent by weight standards for #2 distillate oil (0.0015% sulfur by weight or 15 part per million (ppm)), #4 residual oil (0.25–0.5% sulfur by weight), and #6 residual oil (0.3–0.5% sulfur by weight). The District explains that, in 2016, EPA approved into the DC SIP the District's regulation to reduce the sulfur content of commercial fuel oil (20 DCMR Section 801). 81 FR 70020 (Oct. 11, 2016). The final rule called for a 2,500 ppm limit (0.25% sulfur by weight) on #4 oil in 2016 and a 15 ppm limit (0.0015% sulfur by weight) on #2 oil starting in 2018. The rule also banned the sale of #5 and #6 fuel oil after July 1, 2016. The emissions reductions expected from implementing the 15 ppm provisions will be achieved during the second implementation period and the ultra low-sulfur fuel oil regulations in the District are a part of its long-term strategy. The District therefore concluded that it is meeting Ask 3.

MANE–VU Ask 4 requests states to update permits to ''lock in'' lower emissions rates for NO_X, SO_2, and PM

[38] See appendix 8 of the DC DOEE 2019 Regional Haze SIP submission, ''Statement of the Mid-Atlantic/Northeast Visibility Union (MANE–VU) States Concerning a Course of Action Within MANE–VU Toward Assuring Reasonable Progress for the Second Regional Haze Implementation Period (2018–2028)'' at 1 August 25, 2017.

[39] *Id.*

[40] *Id.*

[41] The period of 2012–2016 was the most recent period for which data was available at the time of analysis.

[42] See appendix 14 of the DC DOEE 2019 Regional Haze SIP submission, ''Mid-Atlantic/Northeast U.S. Visibility Data 2004–2016 (2nd RH SIP Metrics).''

[43] MANE–VU Four Factor Data Collection Memo at 1, March 30, 2017, *available at https://otcair.org/MANEVU/Upload/Publication/Reports/Four-Factor%20Data%20Collection%20Memo%20-%20170314.pdf.* The six sectors were identified in the first implementation period pursuant to MANE–VU's contribution assessment; MANE–VU subsequently updated its information on these sectors for the second implementation period.

[44] 2016 Updates to the Assessment of Reasonable Progress for Regional Haze in MANE–VU Class I Areas, January 31, 2016, *available at https://s3.amazonaws.com/marama.org/wp-content/uploads/2019/09/13095234/FINAL_Updates_to_4Factor_Reasonable_Progress_Report_2016_01_31.pdf.*

[45] *Id.*

[46] Table 1 of MANE–VU's ''Four Factor Data Collection Memo'' March 30, 2017 contains 2011 SO_2 data from specific sources.

[47] The ''Status of the Top 167 Electric Generating Units (EGUs) that Contributed to Visibility Impairment at MANE–VU Class I Areas during the 2008 Regional Haze Planning Period'' July 25, 2016 reviews the existing and soon to be installed, at the time of the report, emission controls at individual EGU sources that were a part of the MANE–VU Ask from the first implementation period. *Available at: https://otcair.org/MANEVU/Upload/Publication/Reports/Status%20of%20the%20Top%20167%20Stacks%20from%20the%202008%20MANE-VU%20Ask.pdf.*

[48] See appendix 8 of the DC DOEE 2019 Regional Haze SIP submission, ''Statement of the Mid-Atlantic/Northeast Visibility Union (MANE–VU) Concerning a Course of Action within MANE–VU toward Assuring Reasonable Progress for the Second Regional Haze Implementation Period (2018–2028), (August 2017).''

at emissions sources larger than 250 million British Thermal Units (MMBtu) per hour heat input that have switched to lower emitting fuels. According to the District's SIP submission, the only facility in the District that is larger than 250 MMBtu is the U.S. General Services Administration Central Heating and Refrigeration Plant (''GSA Central Heating Plant''). While the facility originally burned coal, in July 2000 it was limited through a federally enforceable Title V permit revision to the use of natural gas, with #2 fuel oil (maximum 0.05% sulfur by weight) to be used only as a back-up fuel when the natural gas supply is interrupted by the supplier. The District stated that no additional updates are needed at the facility for this Ask.

Ask 5 requests that states ''control NO_X emissions for peaking combustion turbines'' (capable of generating 15 MW or more of electricity) ''that have the potential to operate on high electric demand days'' by either (1) meeting NO_X emissions standards specified in the Ask for turbines that run on natural gas and for fuel oil, (2) performing a four-factor analysis for reasonable installation of or upgrade to emission controls, or (3) obtaining equivalent emission reductions on high electric demand days.[49] The District states in its submission that it has no combustion turbines that sell electricity to the grid during high electricity demand days, but also notes that its reasonably available control technology (RACT) rule for combustion turbines, associated heat recovery steam generators, and duct burners that was approved into the SIP on February 24, 2020 (85 FR 10295), applies to *all* combustion turbines in the District regardless of their electricity generation capabilities. The District further explains that its RACT rule, which the District adopted to comply with the NO_X RACT requirements under the 2008 Ozone National Ambient Air Quality Standards (NAAQS), meets the NO_X emission rates that MANE–VU provided states should strive to meet under Ask 5.[50] The District states in its submission that it finds that this RACT rule would comply with Ask 5.

The last Ask for states within MANE–VU (Ask 6) requests states to report in their regional haze SIPs about programs that decrease energy demand and increase the use of combined heat and power (CHP) and other distributed generation technologies such as fuel cells, wind and solar. The District explains in its SIP submission that it ''has a variety of programs and initiatives underway that reduce air pollution through reduced energy use, energy efficiency, cogeneration, or clean distributed generation.'' [51] The SIP submission specifically cites three cogeneration facilities the District has permitted since 2011 as well as its 2006 Green Building Act.

2. EPA's Evaluation of the District's Response to the Six MANE–VU Asks and Compliance With 40 CFR 51.308(f)(2)(i)

EPA is proposing to find that the District has satisfied the requirements of 40 CFR 51.308(f)(2)(i) related to development of a long-term strategy. As explained above, MANE–VU conducted an inventory analysis to identify the source sectors that produced the greatest amount of SO_2 and NO_X emissions in 2011; inventory data were also projected to 2018. Based on this analysis, MANE–VU identified the top-emitting sectors for each of the two pollutants, which for SO_2 include coal-fired EGUs, industrial boilers, oil-fired EGUs, and oil-fired area sources including residential, commercial, and industrial sources. Major-emitting sources of NO_X include on-road vehicles, non-road vehicles, and EGUs.[52] The RPO's documentation explains that ''[EGUs] emitting SO_2 and NO_X and industrial point sources emitting SO_2 were found to be sectors with high emissions that warranted further scrutiny. Mobile sources were not considered in this analysis because any ask concerning mobile sources would be made to EPA and not during the intra-RPO and inter-RPO consultation process among the states and tribes.'' [53] Thus, in selecting sources and source sectors for further analysis, we are proposing to find that the District's reliance on the technical analysis provided by MANE–VU, and adopted by all ''State participants,'' per 40 CFR 51.308(f)(2)(iii), demonstrates that the District reasonably evaluated sources of the two pollutants—SO_2 and NO_X—that drive visibility impairment within the MANE–VU region and that it adequately explained and supported its choice of sources and source categories for further analysis.

Section 51.308(f)(2)(i) requires states to evaluate and determine the emission reduction measures that are necessary to make reasonable progress by applying the four factors to sources. As explained previously, the MANE–VU Asks are a mix of measures for sectors and groups of sources identified as reasonable for states to address in their regional haze plans and requests for states to perform four-factor analyses for specific sources the RPO identified as potentially contributing to visibility impairment. As laid out in further detail below, EPA is proposing to find that MANE–VU's four-factor analysis conducted to support Ask 3, in conjunction with the District's analysis and explanation of how it has either complied with each Ask or determined that it is not applicable, satisfies the requirement to determine the emission reduction measures that are necessary to make reasonable progress by considering the costs of compliance, time necessary for compliance, energy and non-air quality impacts of compliance, and remaining useful life of any potentially affected sources.

The District concluded that it satisfied Ask 1 because it has no coal-fired EGUs with a nameplate capacity of greater than 25 MW. EPA notes that Ask 1 does not refer exclusively to coal-fired EGUs; however, a review of the NEI and Clean Air Markets Division data shows that the District does not have any EGUs with a capacity greater than 25 MW.[54] EPA therefore proposes to find that the District's conclusion that it is currently meeting Ask 1 is reasonable.

Ask 2 addresses the sources MANE–VU determined have the potential for ≥3 Mm^{-1} visibility impact at any MANE–VU Class I area; the Ask requests MANE–VU states to conduct four-factor analyses for the specified sources within their borders. This Ask explicitly engages with the statutory and regulatory requirement to determine reasonable progress based on the four factors; MANE–VU considered it ''reasonable to have the greatest contributors to visibility impairment conduct a four-factor analysis that would determine whether emission control measures should be pursued and what would be reasonable for each source.'' [55]

The District did not conduct a four-factor analysis for any individual point

[49] See appendix 8 of the DC DOEE 2019 Regional Haze SIP submission.

[50] See Section V of this proposed rulemaking for a discussion of the correction that EPA is proposing for the DC NO_X RACT rule.

[51] See section 2.5.6 of the DC DOEE 2019 Regional Haze SIP submission at 16.

[52] See ''Contribution Assessment Preliminary Inventory Analysis (October 10, 2016)'' *available at: https://otcair.org/MANEVU/Upload/Publication/Reports/Contribution%20Assessment%20Preliminary%20Inventory%20Analysis.pdf.*

[53] See appendix 7 of the DC DOEE 2019 Regional Haze SIP submission, ''MANE–VU Regional Haze Consultation Report'' at 3, July 27, 2018.

[54] EPA notes that the GSA Central Heating Plant and Capital Power Plant are not considered EGUs and therefore finds it reasonable that the District did not include them in its consideration of Ask 1.

[55] Id at 4.

sources of visibility-impairing pollutants. It is relevant to our evaluation of the reasonableness of this decision that not only did MANE–VU not identify any large EGUs or other industrial sources of visibility impairing pollutants within the District, the District does not actually contain any point sources with large emissions of visibility impairing pollutants. The 2014 NEI data included in the District's submission show that total actual point source emissions for SO_2 District-wide were less than 50 tons and less than 500 tons for NO_X. Data EPA pulled from the 2017 NEI show that total actual point source emissions for SO_2 District-wide were less than 30 tons and less than 400 tons for NO_X.[56] That the District's emissions are this low on a jurisdiction-wide basis reinforces the reasonableness of the its decision to not apply the four factors to any individual point source of visibility impairing pollutants in the second implementation period.

The District does contain one source that is >250 MMBtu/hour, the GSA Central Heating Plant; a steam plant and refrigeration facility (produces both steam for heat and process energy and chilled water for refrigeration) that also uses co-generation to produce both heat energy and electricity for use on site. The GSA Central Heating Plant is the largest point source of emissions (by combined NO_X and SO_2 emissions) in the District as reported under the NEI. It was also the subject of the NPS's 2018 early engagement source evaluation request in which that agency provided a list of sources and requested that states review and consider those sources for inclusion in their long-term strategies.[57] For the following reasons, EPA believes the District reasonably declined to conduct a four-factor analysis for the GSA Central Heating Plant.[58] First, as reported under the 2017 NEI, the GSA Central Heating Plant's total emissions are relatively low at 127 tons per year NO_X and 0.6 tons per year SO_2.[59] Second, emissions from the source are already subject to both operational limits and enforceable emission limits including the District's NO_X RACT rule, which has been adopted into its SIP.[60] The Plant's NO_X emissions come from five boilers and one cogeneration system that is comprised of two combustion turbine generators, one heat recovery steam generator, and duct burners.[61] Each of the five boilers is equipped with low NO_X burners or dry low NO_X burners [62] and is limited by the source's Title V permit (permit No. 032) to burning natural gas except for periods of service interruption, when the boilers are permitted to burn #2 fuel oil.[63] The 15 ppm low sulfur fuel oil rule applies to any fuel oil that would be used at the GSA Central Heating Plant. The boilers, three of which are rated at 250 MMBtu/hour and two of which are rated at 500 MMBtu/hour, are additionally limited under the NO_X RACT rule to 0.25 lb NO_X/MMBtu when powered by fuel oil or a combination of oil and natural gas, and 0.2 lb NO_X/MMBtu when powered by natural gas. The two larger boilers, as well as the cogeneration unit, are further subject to a cap of 25 tons of NO_X total per ozone season; this cap was required pursuant to EPA's NO_X SIP call and has been approved into the District's SIP.[64] The combustion turbines that are part of the GSA Central Heating Plant's cogeneration system are also limited to burning natural gas except for periods of service interruption, when they are permitted to burn #2 fuel oil. The turbines are inherently low emitting by virtue of their dry low NO_X burners and emissions are also limited by the NO_X RACT rule, which contains requirements for combustion turbines and associated heat recovery steam generators and duct burners equivalent to the New Source Performance Standards (NSPS) in subpart KKKK. The duct burners at the GSA Central Heating Plant are fired exclusively on natural gas.[65] Based on the fact that the GSA Central Heating Plant's emissions are already relatively low and controlled as the result of SIP-based limits on SO_2 (low sulfur fuel oil rule) and NO_X (NO_X RACT rule and limits related to NO_X SIP call), EPA believes it was reasonable for the District not to conduct a four-factor analysis for this source, whether or not it was on the MANE–VU list of sources pursuant to Ask 2.

Ask 3, which addresses the sulfur content of heating oil used in MANE–VU states, is based on a four-factor analysis for the heating oil sulfur reduction regulations contained in that Ask;[66] specifically, for reducing the sulfur content of distillate oil to 15 ppm. The analysis started with an assessment of the costs of retrofitting refineries to produce 15 ppm heating oil in sufficient quantities to support implementation of the standard, as well as the impacts of requiring a reduction in sulfur content on consumer prices. The analysis noted that, as a result of previous EPA rulemakings to reduce the sulfur content of on-road and non-road-fuels to 15 ppm, technologies are currently available to achieve sulfur reductions and many refiners are already meeting this standard, meaning that the capital investments for further reductions in the sulfur content of heating oil are expected to be relatively low compared to costs incurred in the past. The analysis also examined, by way of example, the impacts of New York's existing 15 ppm sulfur requirements on heating oil prices and concluded that the cost associated with reducing sulfur was relatively small in terms of the absolute price of heating oil compared to the magnitude of volatility in crude oil prices. It also noted that the slight price premium is compensated by cost savings due to the benefits of lower-sulfur fuels in terms of equipment life and maintenance and fuel stability. Consideration of the time necessary for compliance with a 15 ppm sulfur standard was accomplished through a discussion of the amount of time refiners had needed to comply with EPA's on-road and non-road fuel 15 ppm requirement, and the implications existing refinery capacity and distribution infrastructure may have for compliance times with a 15 ppm heating oil standard. The analysis concluded that with phased-in timing for states that have not yet adopted a 15 ppm heating oil standard there ''appears to be sufficient time to allow refiners to add any additional heating oil capacity that may be required.'' [67] The analysis further noted the beneficial energy and non-air quality environmental impacts

[56] See ''2017 National Emissions Inventory Data for the District of Columbia for Select Pollutants'' in the docket.

[57] See appendix 9 of the DC DOEE 2019 Regional Haze SIP submission, ''National Park Service Letter to MANE–VU (April 2018).''

[58] The District's response to the NPS's early engagement request is contained in section 2.5.7. of the DC DOEE 2019 Regional Haze SIP submission at 17.

[59] See ''2017 National Emissions Inventory Data for the District of Columbia for Select Pollutants'' in the docket.

[60] 85 FR 10295 (February 24, 2020). The District's NO_X RACT rule went into effect on July 23, 2018.

[61] The District of Columbia's DOEE SIP Submission on Reasonably Available Control Technology (RACT) for Oxides of Nitrogen (NO_X) Determination for the 2008 8-Hour Ozone National Ambient Air Quality Standards (NAAQS) (''DC DOEE 2018 NO_X RACT submission'') at 5–6, August 29, 2018. (February 24, 2020, 85 FR 10295).

[62] DC DOEE 2018 NO_X RACT submission at 5–6.

[63] Section 2.5.7 of the DC DOEE 2019 Regional Haze SIP submission at 18.

[64] 81 FR 8656 (February 22, 2016); DC DOEE 2018 NO_X RACT Submission at 9.

[65] DC DOEE 2019 Regional Haze SIP submission at 17–18; DC DOEE 2018 NO_X RACT submission at 15.

[66] See ''2016 Updates to the Assessment of Reasonable Progress for Regional Haze in MANE–VU Class I Areas'' at 8–4, January 31, 2016, *available at: https://s3.amazonaws.com/marama.org/wp-content/uploads/2019/09/13095234/FINAL_Updates_to_4Factor_Reasonable_Progress_Report_2016_01_31.pdf.*

[67] *Id.* at 8–7.

of a 15 ppm sulfur heating oil requirement and that reducing sulfur content may also have a salutary impact on the remaining useful life of residential furnaces and boilers.[68]

EPA proposes to find that the District reasonably relied on MANE–VU's four-factor analysis for a low-sulfur fuel oil regulation, which engaged with each of the factors and explained how the information supported a conclusion that a 15 ppm-sulfur fuel oil standard is reasonable. The agency further proposes to determine that the District's SIP-approved ultra-low sulfur fuel oil rule satisfies the requirement of 40 CFR 51.308(f)(2) that its long-term strategy include the enforceable measures that are necessary to make reasonable progress, as determined through consideration of the four factors.[69]

The District concluded that no additional updates were needed to meet Ask 4, which requests MANE–VU states to pursue updating permits, enforceable agreements, and/or rules to lock-in lower emission rates for sources >250 MMBtu per hour that have switched to lower emitting fuels. As explained above, the GSA Central Heating Plant is the only point source >250 MMBtu per hour in the District. While the boilers were originally configured to burn coal, in 2000 the source updated its Title V permit to limit the source to using only natural gas as a primary fuel and #2 fuel oil during natural gas supply interruptions.[70] Thus, EPA proposes to find that the District reasonably determined it has satisfied Ask 4.

Ask 5 addresses NO_X emissions from peaking combustion turbines that have the potential to operate on high electric demand days. The District notes that, while it has no combustion turbines that sell electricity to the grid during such days, its SIP-adopted NO_X RACT rule applies to all combustion turbines and meets the emission rates contained in Ask 5. EPA therefore proposes to find that the District reasonably concluded that its existing regulations would comply with Ask 5.

Finally, with regard to Ask 6, the District reports three cogeneration facilities it has permitted and describes the provisions of its 2006 Green Building Act. EPA is proposing to find that the District has satisfied Ask 6's request to consider and report in its SIP measures or programs related to energy efficiency, cogeneration, and other clean distributed generation technologies.

In sum, EPA is proposing to find that, based on the District's participation in the MANE–VU planning process, how it has addressed each of the Asks, and EPA's assessment of the District's emissions and point sources, the District has complied with the requirements of 40 CFR 51.308(f)(2)(i). The Agency notes that MANE–VU concluded that sulfates from SO_2 emissions were still the primary driver of visibility impairment in the second implementation period[71] and that MANE–VU conducted a four-factor analysis to support Ask 3, which requests that states pursue ultra-low sulfur fuel oil standards to address SO_2 emissions. The District has done so and included its regulations in its SIP, thus satisfying the requirements that states determine the emission reduction measures necessary to make reasonable progress by considering the four factors and that their long-term strategies include the enforceable emission limitations, compliance schedules, and other measures necessary to make reasonable progress. EPA further believes it is reasonable that the District did not examine additional sources for potential emission reduction measures in the second implementation period because there are no large point sources of visibility-impairing pollutants in the jurisdiction; furthermore, the largest category of area sources of SO_2 emissions are oil-fired residential, commercial, and industrial sources that are covered by the fuel oil standard and the largest area source category of NO_X emissions is mobile sources. In particular, EPA believes it was reasonable for the District not to conduct a four-factor analysis for the GSA Central Heating Plant—the largest point source of emissions—because that facility's emissions are already relatively low and, critically, are already limited by SIP-based emission limits, in addition to permit-based fuel requirements. Additionally, to the extent that MANE–VU has identified the measures in Asks 4 through 6 as being part of the region's strategy for making reasonable progress, we propose to find it reasonable for the District to address these Asks by pointing to existing and on-the-way measures that satisfy each.

3. Additional Long-Term Strategy Requirements

EPA also proposes to determine that the District has satisfied the consultation requirements of 40 CFR 51.308(f)(2)(ii). The District participated in and provided documentation of the MANE–VU intra- and inter-RPO consultation processes and addressed each of the MANE–VU Asks, either by explaining why an Ask is not applicable or providing information on the measures it has in place that satisfy an Ask.[72] EPA proposes to find that the District's explanations with regard to Asks 1 and 2, for which the District did not offer any measures pursuant to MANE–VU's requests, are reasonable given the District's lack of sources that fit the applicability criteria for those Asks (EGUs with capacity ≥25 MW and sources with the potential for ≥3.0 m^{-1} visibility impact).

The District chose to rely on MANE–VU's technical information, modeling, and analysis to support development of its long-term strategy. EPA proposes to find that the documentation developed by MANE–VU and provided and referenced by the District in its submission satisfies the requirements of 40 CFR 51.308(f)(2)(iii). As required in 40 CFR 51.308(f)(2)(iii), the emissions information considered to determine what is necessary to make reasonable progress included information on emissions for the most recent year for which the state has submitted triennial emissions data to EPA (or a more recent year), with a 12-month exemption period for newly submitted data. The District's submission includes emissions inventory data from 2014, which was the most recent year of data that the District had submitted to EPA to meet the triennial reporting requirement within 12 months prior to the District's submittal in November 2019.[73] EPA proposes to find that the District has satisfied the emission inventory requirement in 40 CFR 51.308(f)(2)(iii).

EPA also proposes to find that the District considered the five additional factors in 40 CFR 51.308(f)(2)(iv) in developing its long-term strategy. Pursuant to 40 CFR 51.308(f)(2)(iv)(A), the District noted that ongoing federal emission control programs, including boiler and Reciprocating Internal Combustion Engine (RICE) National Emission Standards for Hazardous Air Pollutants (NESHAP) requirements, portable fuel container rules, and New Source Performance Standards (NSPS) for stationary compression ignition engines, would impact emissions from point and nonpoint sources in the

[68] *Id.* at 8–8.

[69] The District notes in its SIP submission, its regulations were incorporated into its SIP on October 11, 2016 (81 FR 70020).

[70] See section 2.5.4 of the DC DOEE 2019 Regional Haze SIP submission.

[71] See section 2.4.2 of the DC DOEE 2019 Regional Haze SIP submission.

[72] The District provided documentation of the MANE–VU consultation process in appendix 5, ''Inter-RPO State/Tribal and FLM Consultation Framework (5/10/2006)'', appendix 6, ''MANE VU Regional Haze Consultation Plan (5/5/2017)'', and appendix 7, ''MANE–VU Regional Haze Consultation Report (7/27/2018)'' of its 2019 Regional Haze SIP submission.

[73] See section 2.20 of the DC DOEE 2019 Regional Haze SIP submission.

second implementation period. For the on-road and non-road source categories, the District identified equipment turnover, fuel requirements, and the transportation conformity regulation (May 28, 2010, 75 FR 29894) as continuing factors that contribute to emission reductions through 2028. On-going measures from various source categories that the District considered in developing its long-term strategy were the NOx emissions budget approved by EPA on February 22, 2016 (81 FR 8656), NOx RACT requirements for Combustion Turbines (February 24, 2020, 85 FR 10295), and the sulfur content of fuel oil rule (October 11, 2016, 81 FR 70020).

The District's consideration of measures to mitigate the impacts of construction activities as required by 40 CFR 51.308(f)(2)(iv)(B) includes discussion of a report that found that, from a regional haze perspective, crustal material from anthropogenic sources does not play a major role in visibility impairment at MANE–VU Class I areas.[74] While construction activities can be responsible for direct PM emissions in the region, the dust settles out of the air relatively close to the sources and does not impact visibility at distant Class I areas significantly. The District cited its 'Control of Fugitive Dust' regulation which requires reasonable precautions to minimize emissions of fugitive dust (August 28, 1995, 60 FR 44431) as one measure used to control PM emissions in the District. A summary of the PM emission inventory in the District can be found in Section IV.H. of this rulemaking.[75]

Source retirements and replacement schedules are addressed pursuant to 40 CFR 51.308(f)(2)(iv)(C) in section 2.7.3 of the District's submission. The shutdown of only one large EGU or industrial source in the District—the Pepco Benning Road Generation Station, which retired in 2012—is reflected in the emissions inventories used for the MANE–VU contribution assessment. In addressing smoke management as required in 40 CFR 51.308(f)(2)(iv)(D), the District explained that it is an urban area and does not have agricultural or prescribed forest burns and thus does not have a smoke management plan.[76] The District also asserts that additional measures to mitigate smoke emissions from agricultural and forest fires are not needed in its SIP, although the submission does cite a regulation that limits seasonal open burning (August 28, 1995, 60 FR 44431).

The District discussed its consideration of the anticipated net effect of projected changes in emissions as required by 40 CFR 51.308(f)(2)(iv)(E) by explaining how MANE–VU's visibility modeling for 2028 incorporates such projected changes. MANE–VU conducted photochemical modeling for the 2018–2028 implementation period after consultation with states within and outside of the RPO. The 2028 base case considers only on-the-books controls, and a 2028 control case considers implementation of the MANE–VU Asks. For the District, the 2028 base-case modeling included the District's measures pursuant to Asks 4 and 5, while the low sulfur fuel oil measure consistent with Ask 3 was included only in the 2028 control case modeling. The SIP revision notes the projected visibility conditions in five Class I areas—Brigantine Wilderness, Otter Creek/Dolly Sods Wildernesses, James River Face Wilderness, and Shenandoah National Park—on the most impaired and clearest days under the 2028 base case.[77]

Because the District has considered each of the five additional factors, discussed the measures it has in place to address each (or discussed why such measures are not needed), and, where relevant, explained how each factor informed MANE–VU's technical analysis for second implementation period planning for reasonable progress, EPA proposes to find that the District has satisfied the requirements of 40 CFR 51.308(f)(2)(iv).

F. Reasonable Progress Goals

Section 51.308(f)(3)(i) requires a state in which a Class I area is located to establish reasonable progress goals-one each for the most impaired and clearest days-reflecting the visibility conditions that will be achieved as a result of implementing the long-term strategy. The District is not required to establish RPGs because it does not have a Class I area.

Section 51.308(f)(3)(ii) applies in circumstances in which a Class I area's RPG for the most impaired days represents a slower rate of visibility improvement than the uniform rate of progress calculated under 40 CFR 51.308(f)(1)(vi). Under 40 CFR 51.308(f)(3)(ii)(B), a state that contains sources that are reasonably anticipated to contribute to visibility impairment in such a Class I area must demonstrate that there are no additional emission reduction measures that would be reasonable to include in its long-term strategy. The District's SIP revision included the modeled MANE–VU 2028 visibility projections at nearby Class I areas.[78] While these projections may not represent the final RPGs for these Class I areas, all of the 2028 projections for the most impaired days at these areas (Brigantine, Dolly Sods/Otter Creek, Shenandoah, and James River Face) are well below the respective 2028 glidepaths. In addition, we note that the District's largest contribution is to Brigantine Wilderness in New Jersey. New Jersey submitted its regional haze SIP to EPA on March 26, 2020 and the proposed RPG for Brigantine was also well below the 2028 glidepath.[79] EPA proposes to determine that the District has satisfied the applicable requirements of 40 CFR 51.308(f)(3) relating to reasonable progress goals.

G. Monitoring Strategy and Other Implementation Plan Requirements

Section 51.308(f)(6) specifies that each comprehensive revision of a state's regional haze SIP must contain or provide for certain elements, including monitoring strategies, emissions inventories, and any necessary reporting and recordkeeping measures needed to assess and report on visibility. A main requirement of this subsection is for states with Class I areas to submit monitoring strategies for measuring, characterizing, and reporting on visibility impairment. The District does not have a Class I area and therefore its SIP is not required to provide for a monitoring strategy and associated requirements. It is also not subject to the requirements of 40 CFR 51.308(f)(6)(i), (ii), and (iv), which apply only to states with Class I areas and pertain to the establishment of monitoring sites and reporting and use of monitoring data. However, the District's SIP is required to provide for procedures by which monitoring data and other information are used in determining the contribution to emissions to visibility impairment in other states. 40 CFR 51.308(f)(6)(iii). Pursuant to this requirement, the

[74] See appendix 12 of the DC DOEE 2019 Regional Haze SIP submission, ''The Nature of the Fine Particle and Regional Haze Air Quality Problems in the MANE–VU Region: A Conceptual Description (NESCAUM, November 2006, Revised August 2010)'' at 3–8 of section 3.1.4.

[75] Section 2.20.2 of the DC DOEE 2019 Regional Haze SIP submission addresses the PM_{10} inventory for DC.

[76] See section 2.7.4 of the DC DOEE 2019 Regional Haze SIP submission at 24.

[77] See appendix 11 or section 2.22 of the DC DOEE 2019 Regional Haze SIP submission.

[78] Section 2.22 of the DC DOEE 2019 Regional Haze SIP submission.

[79] New Jersey submitted its second regional haze SIP on March 26, 2020 and supplemented the documentation on September 8, 2020. At the time of this document, EPA has not yet proposed to approve or disapprove New Jersey's determination with regard to the RPGs for Brigantine Wilderness Area.

District commits to continuing support of ongoing IMPROVE visibility monitoring in Class I areas.[80]

The District asserts that it is subject only to the requirements of 40 CFR 51.308(f)(6)(iii).[81] EPA disagrees with this statement; the District is also subject to 40 CFR 51.308(f)(6)(v) and (vi), which apply to all states regardless of whether it has a Class I area. Despite the District's misstatement, EPA is proposing to find that its SIP provides for the necessary elements to satisfy the applicable requirements.

Section 51.308(f)(6)(v) requires each state, including states without Class I areas, to provide for an inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment, including emissions for the most recent year for which data are available and estimates of future projected emissions. It also requires a commitment to update the inventory periodically. The District provides for emissions inventories and estimates for future projected emissions by participating in the MANE–VU RPO and complying with the AERR. In 40 CFR part 51, subpart A, the AERR requires states and the District of Columbia to submit emissions inventories for criteria pollutants to EPA's Emissions Inventory System (EIS) every three years. The emission inventory data is used to develop the NEI, which provides for a triennial state-wide inventory of pollutants that are reasonably anticipated to cause or contribute to visibility impairment. MANE–VU also developed projections of future emissions of visibility impairing pollutants and in its submission the District commits to continue coordinating with MANE–VU on progress reports, SIP revisions, and face-to-face consultation meetings as necessary to maintain and improve the visibility in Class I Federal areas.[82]

Section 2.20 of the District's second implementation period regional haze SIP submission includes tables of National Emissions Inventory (NEI) data. The source categories of the emissions inventories included are: (1) Point sources; (2) nonpoint sources; (3) non-road mobile sources; and (4) on-road mobile sources. The point source category is further divided into Air Markets Program Data (AMPD) point sources and non-AMPD point sources.[83] The District included NEI emissions inventories for the following years: 2002 (one of the regional haze program baseline years), 2008, 2011, and 2014; and for the following pollutants: SO_2, NO_X, PM_{10}, and NH_3. The District's SIP revision was submitted in November 2019 and the 2017 NEI was not published until 2020; therefore, the year of the most recent NEI at the time of submission to EPA was 2014. There are additional data from the years of 2016 and 2017 for SO_2 and NO_X from the only AMPD source listed in the District: The GSA Central Heating Plant. While not included in its regional haze submission, the District has a complete NEI for 2017.

As required in 40 CFR 51.308(f)(6)(v), states must commit to update the inventory of emissions of pollutants that are reasonably anticipated to cause or contribute to visibility impairment periodically. The District chose to rely on the NEI as the inventory of these emissions. Under the AERR, states are required to submit estimates for all emissions categories to EPA on a three-year cycle. EPA finds that the requirements to periodically update the national inventory for all emission categories suffices to meet the requirement to commit to updating a visibility impairing pollutant inventory for the District.

Section 51.308(f)(6)(v) also requires states to include estimates of future projected emissions and include a commitment to update the inventory periodically. The District explains in its submission that MANE–VU projected emissions to 2028, which is the end of the second implementation period.[84] MANE–VU completed two 2028 projected emissions modeling cases—a 2028 base case that considers only on-the-books controls and a 2028 control case that considers implementation of the MANE–VU Asks.[85] For the District, the only emission reductions from new measures included in the control case was implementation of the low sulfur fuel oil standard Ask 3. EPA proposes that the District has met the requirements of 40 CFR 51.308(f)(6)(v) by its continued participation in MANE–VU and on-going compliance with the AERR, and that no further elements are necessary at this time for the District to assess and report on visibility pursuant to 40 CFR 51.308(f)(6)(vi).

H. Requirements for Periodic Reports Describing Progress Towards the Reasonable Progress Goals

Section 51.308(f)(5) requires that periodic comprehensive revisions of states' regional haze plans also address the progress report requirements of 40 CFR 51.308(g)(1) through (5). The purpose of these requirements is to evaluate progress towards the reasonable progress goal for each Class I area within the state and each Class I area outside the state that may be affected by emissions from within that state. Section 51.308(g)(1) and (2) apply to all states and require a description of the status of implementation of all measures included in a state's first implementation period regional haze plan and a summary of the emission reductions achieved through implementation of those measures. Section 51.308(g)(3) applies only to states with Class I areas within their borders and requires such states to assess current visibility conditions, changes in visibility relative to baseline (2000–2004) visibility conditions, and changes in visibility conditions relative to the period addressed in the first implementation period progress report. Section 51.308(g)(4) applies to all states and requires an analysis tracking changes in emissions of pollutants contributing to visibility impairment from all sources and sectors since the period addressed by the first implementation period progress report. This provision further specifies the year or years through which the analysis must extend depending on the type of source and the platform through which its emission information is reported. Finally, 40 CFR 51.308(g)(5), which also applies to all states, requires an assessment of any significant changes in anthropogenic emissions within or outside the state have occurred since the period addressed by the first implementation period progress report, including whether such changes were anticipated and whether they have limited or impeded expected progress towards reducing emissions and improving visibility.

The District's submission describes the status of the measures of the long-term strategy from the first implementation period and contains a summary of the emission reductions achieved by implementing those

[80] Section 2.15 of the DC DOEE 2019 Regional Haze SIP submission at 28.

[81] *Id.*

[82] See Executive Summary at vii and section 1.5 at 4 of the DC DOEE 2019 Regional Haze SIP submission.

[83] AMPD sources are facilities that participate in EPA's emission trading programs. The majority of AMPD sources are electric generating units (EGUs).

[84] See section 2.6 of the DC DOEE 2019 Regional Haze SIP submission.

[85] The District cites these as appendices 9 and 10 in the document, but they are ''Technical Support Document for the 2011 Northeastern U.S. Gamma Emission Inventory (January 2018)'' appendix 10 and ''Ozone Transport Commission/Mid-Atlantic Northeastern Visibility Union 2011 Based Modeling Platform Support Document—October 2018 Update (October 2018)'' appendix 11 in the SIP submission respectively.

measures.[86] As a member of MANE–VU, the District considered the MANE–VU Asks and adopted corresponding measures into its long-term strategy for the first implementation period.

One of the MANE–VU Asks from the first implementation period was for states to address emissions from 167 EGUs across the middle and eastern United States. The District did not have any of those sources within its borders, and so did not incorporate any measures in response to this Ask into its plan. The District did have two units that met the eligibility requirements for BART, but the facility—the Pepco Benning Road Generation Station—took enforceable permit conditions to shut down both units in 2012 and therefore did not undergo BART determinations. The shutdown met another of the MANE–VU Asks, *i.e.,* timely implementation of BART, by elimination of the would-be BART sources and their emissions from the inventory entirely. The emission reductions achieved through these source closures are summarized in the source retirement section of the submission.[87] Lastly, in response to a MANE–VU Ask in 2015 the District promulgated a rule to reduce the sulfur content in commercial heating oil and to prohibit the use of heavy heating oils that contain high levels of sulfur. EPA approved this rule into the SIP on May 1, 2017. 82 FR 20270. The SO_2 and NO_X emission reductions achieved by implementing this measure are presented in section 2.18 of the District's submission.

EPA proposes to find that the District has met the requirements of 40 CFR 51.308(g)(1) and (2) because its SIP submission describes the measures included in the long-term strategy from the first implementation period, as well as the status of their implementation and the emission reductions achieved through such implementation.

Section 51.308(g)(3) requires states with Class I areas to report on the visibility conditions and changes at those areas. The District does not have any Class I areas and is not required to address this provision.

Pursuant to 40 CFR 51.308(g)(4), the District provided a summary of emissions of SO_2, NO_X, PM_{10}, and NH_3 from all sources and activities, including from point, nonpoint, non-road mobile, and on-road mobile sources, for the time period from 2002 to 2014.[88] The District explained that 2014 was the most recent year for which it had submitted emission estimates to fulfill the requirements of part 51 subpart A (the AERR).

The emissions information submitted by the District indicates that SO_2 emissions decreased over the 2002 through 2014 period. Due to source retirements, the District had zero tons of SO_2 emissions in 2014 from EGUs that report to EPA's AMPD and the submission indicates these emissions continued to be zero in 2016 and 2017. SO_2 emissions from non-AMPD point sources and nonpoint, non-road, and on-road sources all declined steadily from 2002 to 2014.[89]

Total NO_X emissions have also declined from 2002 to 2014, although not all categories have shown a consistent decrease. Reductions in NO_X emissions from AMPD sources are primarily due to EGU retirements, while reductions in non-road and on-road NO_X are due to a range of federal requirements for different types of engines and fuels.[90]

Emissions of PM_{10} decreased overall from 2002 to 2014, with point, nonpoint, and non-road categories having lower emissions in 2014 and on-road sources showing an increase in PM_{10} emissions. Similarly, NH_3 emissions in the District were lower overall in 2014 relative to 2002, although emissions from nonpoint sources do show an increase relative to the baseline.[91]

EPA is proposing to find that the District has satisfied the requirements of 40 CFR 51.308(g)(4) by providing emissions information for SO_2, NO_X, PM_{10}, and NH_3 broken down by type of source. At the time of the District's SIP submission, the year of the most recent data submitted to NEI was 2014; therefore, the endpoint of the analysis of changes in emissions is 2014. The District also provided SO_2 and NO_X data for sources that report to EPA's AMPD for 2016 and 2017.

The District uses the emissions trend data to support the assessment that anthropogenic haze-causing pollutant emissions in the District have decreased during the reporting period and that changes in emissions have not limited or impeded progress for the regional haze program. EPA is proposing to find that the District has met the requirements of 40 CFR 51.308(g)(5).

I. Requirements for State and Federal Land Manager Coordination

Section 51.308(i)(2)'s FLM consultation provision requires that a state must provide FLMs with an opportunity for consultation that is early enough in the state's policy analyses of its long-term strategy emission reduction obligation for the FLMs' input to meaningfully inform the state's decisions. If the consultation has taken place at least 120 days before a public hearing or public comment period, the opportunity for consultation will be deemed early enough, however, the opportunity for consultation must be provided at least sixty days before a public hearing or public comment period at the state level. Section 51.308(i)(2) also provides two substantive topics which FLMs must be provided an opportunity to discuss with states, and 40 CFR 51.308(i)(3) requires states, in developing their implementation plans, to include a description of how they addressed FLMs' comments.

The states in the MANE–VU RPO conducted FLM consultation early in the planning process concurrent with the state-to-state consultation that formed the basis of the RPO's decision making process. As part of the consultation, the FLMs were given the opportunity to review and comment on the technical documents developed by MANE–VU. The FLMs were invited to attend the intra- and inter-RPO consultations calls among states and at least one FLM representative was documented to have attended seven intra-RPO meetings and all inter-RPO meetings. The District participated in these consultation meetings and calls.[92]

As part of this early engagement with the FLMs, in April 2018 the NPS sent letters to the MANE–VU states requesting that they consider evaluating particular sources for inclusion in their long-term strategies.[93] The sources the NPS identified were selected based on a Q/d analysis it performed using cumulative NO_X and SO_2 emissions as the quantity variable Q and the distance to the nearest national park as the variable d. Sources with a Q/d greater than or equal to 1 were included on the 2018 NPS source list; the GSA Central Heating Plant met this threshold based on 2014 NEI data and its proximity to

[86] Section 2.17 of the DC DOEE 2019 Regional Haze SIP submission.

[87] Section 2.7.3 of the DC DOEE 2019 Regional Haze SIP submission.

[88] See ''2017 National Emissions Inventory Data for the District of Columbia for Select Pollutants'' in the docket.

[89] See section 2.20.3 of the DC DOEE 2019 Regional Haze SIP submission.

[90] See section 2.20.2 of the DC DOEE 2019 Regional Haze SIP submission.

[91] See section 2.20.1 of the DC DOEE 2019 Regional Haze SIP submission.

[92] See appendix 7 of the DC DOEE 2019 Regional Haze SIP submission, ''MANE–VU Regional Haze Consultation Summary (MANE–VU, July 2018).''

[93] See appendix 9 of the DC DOEE 2019 Regional Haze SIP submission, ''National Park Service Letter to MANE–VU (April 2018).''

Shenandoah National Park. The District noted that the NPS's methodology did not account for meteorological considerations such as wind direction, and that it disagreed with the NPS's conclusion that the GSA Central Heating Plant was reasonably anticipated to impair visibility at Shenandoah National Park. However, the District decided to respond to the consultation request by explaining the existing emission control measures at the facility. The District's explanation is summarized in section IV.E.2. of this document (addressing EPA's evaluation of the District's response to MANE–VU Ask 2).

On April 10, 2019, the District submitted a draft Regional Haze SIP to the U.S. Forest Service, the U.S. Fish and Wildlife Service, and the National Park Service for a 60-day review and comment period pursuant to 40 CFR 51.308(i)(2).[94] The U.S. Forest Service commented that the draft it received was acceptable and no changes were needed.[95] The National Park Service and the U.S. Fish and Wildlife Service did not provide comments during this consultation period. The District published its regional haze SIP in the District of Columbia Register for a 30-day comment period within the District on August 30, 2019. A public hearing was held on September 30, 2019. No comments were received. Consistent with 40 CFR 51.308(i)(2), the opportunity for FLM consultation took place more than 120 days prior to holding any public hearing.

For the reasons stated above, EPA proposes to find that the District has met its requirements under 40 CFR 51.308(i) to consult with the FLMs on its regional haze SIP for the second implementation period. The District committed in its SIP to ongoing consultation with the FLMs on regional haze issues throughout the implementation period, consistent with the requirement of 40 CFR 51.308(i)(4).[96]

V. Error Correction

A. What is EPA's authority to correct errors in SIP rulemakings?

Section 110(k)(6) of the CAA provides EPA with authority to make corrections to prior SIP actions that are subsequently found to be in error in the same manner as the prior action, and to do so without requiring any further submission from the state. This determination and the basis must be provided to the state and the public.

B. What rule is EPA proposing to correct?

EPA approved the District's revision to the DC NO_X RACT rule (20 DCMR 805) into the SIP on February 24, 2020 (85 FR 10295). The revisions to that rule amended the regulation to remove old provisions and replace them with new and/or more stringent regulations or controls for combustion turbines and associated heat recovery steam generators and duct burners and amended the applicability provisions of these regulations to include all combustion turbines and associated heat recovery steam generators and duct burners, among other related revisions and updates to the rule.

After we finalized the rulemaking, EPA discovered that we had erred in identifying the particular sections of the DC NO_X RACT rule for incorporation by reference into the DC SIP. In several instances, the substance of the District's revisions to its rule in section 805.4(a) and (b) were correctly represented and evaluated in EPA rulemaking, but were cited as being in section 805.1 of the DC NO_X RACT rule. The District also submitted revisions to section 805.1(a) and 805.1(a)(2), which were appropriately discussed and correctly cited in the rulemaking (see 84 FR at 47918, September 11, 2019). Throughout the prior rulemaking we incorrectly referred to section 805.4 as being section 805.1 in both in the narrative and regulatory table.

C. What action is EPA proposing?

EPA is proposing to use our authority under CAA section 110(k)(6) to correct errors in the regulatory citation in our February 24, 2020 final action on the DC NO_X RACT rule and to codify this correction by revising the appropriate entries under 40 CFR 52.470 (Identification of Plan). EPA previously proposed and took public comment on the substance of the DC NO_X RACT rule and our evaluation thereof in the September 11, 2019 NPRM (84 FR 47914). Because this proposed rulemaking is limited to correcting our error in conflating the citations for 805.1 and 805.4, the scope of our present request for comment is limited to whether we are properly effectuating this correction and we will not be taking comment on the substance of the DC NO_X RACT rule. Therefore, as required in CAA section 110(k)(6), in the same manner as the prior action, EPA is proposing for public review and comment the correction to the citations of the provisions which were approved in the previous action. Specifically, we are proposing to amend the table in paragraph (c) of 40 CFR 52.470 to correctly reflect our approval of 20 DCMR sections 805.1(a), 805.1(a)(2), 805.4(a) and 805.4(b), as described in our February 24, 2020 final rule action. This proposal is separate from the proposal to approve the DC DOEE 2019 Regional Haze SIP submission, and as such EPA is taking public comments on the citation correction through this docket, but as a severable action.

VI. Proposed Action

EPA is proposing to approve the revision to the District of Columbia SIP submitted by the District through DC DOEE on November 8, 2019. EPA is proposing to approve the District's SIP submission as satisfying the regional haze requirements for the second implementation period.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Public Law 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or

[94] See appendix 15 of the DC DOEE 2019 Regional Haze SIP submission, ''FLM Consultation Initiation Letter (April 2019).''

[95] See appendix 17 of the DC DOEE 2019 Regional Haze SIP submission, ''US Forest Service Consultation Response Letter (June 2019).''

[96] See section 2.28 of the DC DOEE 2019 Regional Haze SIP submission at 43.

safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this proposed rulemaking, the District's regional haze state implementation plan for the second implementation period and correction for the RACT rule for major stationary sources of NO_X, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the State, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Particulate matter, Sulfur oxides.

Dated: April 5, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

[FR Doc. 2021–07334 Filed 4–14–21; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 59

RIN 0937–AA11

Ensuring Access to Equitable, Affordable, Client-Centered, Quality Family Planning Services

AGENCY: Office of the Secretary, U.S. Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: The Office of Population Affairs (OPA), in the Office of the Assistant Secretary for Health, proposes to revise the rules issued on March 4, 2019, establishing standards for compliance by family planning services projects authorized by Title X of the Public Health Service Act. Those rules have undermined the public health of the population the program is meant to serve. The Department proposes to revise the 2019 rules by readopting the 2000 regulations, with several modifications needed to strengthen the program and ensure access to equitable, affordable, client-centered, quality family planning services for all clients, especially for low-income clients.

DATES: To ensure consideration, comments must be received by May 17, 2021.

ADDRESSES: You may submit comments, identified by Regulatory Information Number 0937–AA11, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Enter the above docket ID number in the ''Enter Keyword or ID'' field and click on ''Search.'' On the next web page, click on ''Submit a Comment'' and follow the instructions.
- *Mail or Hand Delivery [For paper, disk, or CD–ROM submissions] to:* Attn: Title X Rulemaking, Office of Population Affairs, Office of the Assistant Secretary for Health, U.S. Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201. Comments, including any personally identifiable or confidential businesses information, received prior to the close of the comment period will be posted without change to *http://www.regulations.gov.*

While the Department welcomes comments on any aspect of the regulations, we particularly welcome comments concerning how the current regulations have impacted the public's health or how this proposal to revise them will promote public health and aid in the program's fundamental mission to offer a broad range of effective family planning methods with priority given to clients from low-income families.

FOR FURTHER INFORMATION CONTACT: Alicia Richmond Scott, Office of Population Affairs, Office of the Assistant Secretary for Health, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; telephone: 240–453–2800; email: *Alicia.richmond@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Title X of the Public Health Service Act (PHS Act or the Act) (42 U.S.C. 300 through 300a–6) was enacted in 1970 by Public Law 91–572 as a means of ''making comprehensive voluntary family planning services readily available to all persons desiring such services.'' [1] Section 1001 of the Act (42 U.S.C. 300(a)), as amended, authorizes the Secretary of Health and Human Services ''to make grants to and enter into contracts with public or nonprofit private entities to assist in the establishment and operation of voluntary family planning projects which shall offer a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents).'' Section 1006 of the Act (42 U.S.C. 300a–4) ensures that priority of services is given to clients from low-income families and authorizes the Secretary to promulgate regulations governing the program.

Enacted as part of the original Title X legislation, Section 1008 of the Act (42 U.S.C. 300a–6) directs that ''None of the funds appropriated under this title shall be used in programs where abortion is a method of family planning.'' The Conference Report accompanying the legislation described the intent of this provision as follows:

> It is, and has been, the intent of both Houses that funds authorized under this legislation be used only to support

[1] Public Law 91–572 (''The Family Planning Services and Population Research Act of 1970''), section 2(1).

preventive family planning services, population research, infertility services and other related medical, information, and educational activities. The conferees have adopted the language contained in section 1008, which prohibits the use of such funds for abortion, in order to make clear this intent.

H.R. Rep. No 91–1667, at 8–9 (1970) (Conf. Rep.). This requirement has been reiterated by later Congresses through annual appropriations provisos that state: ''[A]mounts provided to said [voluntary family planning] projects under such title shall not be expended for abortions.'' *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, 134 Stat 1182, 1570.

Since 1970 when Title X was first enacted, Congress has amended the law several times both through changes to the Title X statute itself and through yearly appropriations riders. For example, in 1975, Congress amended Title X to include ''natural family planning methods'' as part of the broad range of family planning methods to be offered by Title X projects.[2] PHS Act 1001(a) (42 U.S.C. 300(a)). In 1978, Congress amended Title X to codify HHS past practice by specifically requiring that Title X projects include ''services for adolescents.'' [3] PHS Act 1001(a) (42 U.S.C. 300(a)). The Act was again amended in 1981 to provide that ''[t]o the extent practicable, entities which receive grants or contracts under this subsection shall encourage family participation in projects under this subsection.'' [4] PHS Act sec. 1001(a) (42 U.S.C. 300(a)).

Congress has also imposed additional requirements through annual appropriations riders. For example, since Fiscal Year (FY) 1996, the annual Title X appropriation includes the proviso that ''all pregnancy counseling shall be nondirective.'' [5] *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, 134 Stat 1182, 1570 (2021). Also since FY 1996, the Title X appropriation has directed that Title X funds ''shall not be expended for any activity (including the publication or distribution of literature) that in any way tends to promote public support or opposition to any legislative proposal or candidate for public office.'' *Id.* Since FY 1998, Congress has included a rider in HHS's annual appropriations act that provides that ''[n]one of the funds appropriated in this Act may be made available to any entity under Title X of the PHS Act unless the applicant for the award certifies to the Secretary that it encourages family participation in the decision of minors to seek family planning services.'' [6] *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 207, 134 Stat. 1182, 1590. The same appropriations rider also requires that such an applicant certify to the Secretary that it ''provides counseling to minors on how to resist attempts to coerce minors into engaging in sexual activities.'' *Id.* And, since FY 1999, in a separate rider, Congress has required that, ''[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.'' [7] *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 208, 134 Stat. 1182, 1590 (2021).

II. Regulatory and Litigation Background

The Department first promulgated regulations for the Title X program in 1971 but did not directly address section 1008. 36 FR 18465 (Sept. 15, 1971). With experience, the Department interpreted section 1008 to prohibit grantees [8] from promoting or encouraging abortion as a method of family planning in any way and to require that Title X activities be separate and distinct from any abortion activities. 53 FR 2922, 2923 (Feb. 2, 1988) (describing the Department's interpretation in the early years of the program). In 1981, the Department built upon this experience and issued guidelines directing grantees to provide ''nondirective counseling'' to pregnant clients ''upon request'' including: (1) Prenatal care and delivery; (2) infant care, foster care, or adoption; and (3) pregnancy termination. Counseling included ''referral upon request.'' OPA, Program Guidelines for Project Grants for Family Planning Services at 13 (1981).

In 1988, reacting in large part to a directive from President Reagan, the Department changed course. 53 FR 2922 (Feb. 2, 1988). Regulations promulgated then—commonly called the ''gag rule''—prohibited the discussion of or referral for abortion. The regulations also required grantees to maintain strict physical and financial separation between Title X projects and abortion related activities, to be determined by the ''facts and circumstances'' of each grantee. Additionally, the regulations prohibited lobbying, education, dues-paying, or any other activities which could be interpreted to encourage or promote abortion as a method of family planning.

The 1988 regulations were immediately subject to multiple lawsuits and ultimately upheld by the Supreme Court in *Rust* v. *Sullivan,* 500 U.S. 173 (1991). In *Rust,* the Supreme Court held that section 1008 was ''ambiguous'' and ''at no time did Congress directly address the issues of abortion counseling, referral or advocacy.'' *Id* at 185. The Court was nearly unanimous on this point. *Blackmun dissenting* at 207; O'Connor Dissenting at 223.[9] Given the lack of clarity regarding section 1008, the Court deferred to the Secretary's construction of the statute as ''reasonable'' under *Chevron U.S.A.* v. *NRDC,* 467 U.S. 837 (1984).

The Court also upheld the regulations against constitutional attack under the Fifth and First Amendments. Following recent precedent, the Court held that the Government could constitutionally subsidize some activities over others and that plaintiffs were still free to pursue abortion related activities and speech ''when they are not acting under the auspices of the Title X project.'' *Id.* at 199.

On November 5, 1991, responding to widespread concerns over the regulation's overreach into the doctor-patient relationship, President Bush issued a directive to the Department to allow for open communications between doctors and patients for all aspects of their medical condition. *See Nat'l Family Planning & Reprod. Health Ass'n* v. *Sullivan,* 979 F.2d 227 (D.C. Cir 1992). However, the Department did not engage in rulemaking to carry out the directive, as required by the Administrative Procedure Act. Therefore, the D.C. Court of Appeals

[2] Public Law 94–63.

[3] Public Law 95–613. The amendment reflected Congress' intent to place ''a special emphasis on preventing unwanted pregnancies among sexually active adolescents.'' S. Rep. No 822, 95th Cong, 2d sess. 24 (1978).

[4] Omnibus Budget Reconciliation Act of 1981, Public Law 97–35, sec. 931(b)(1), 95 Stat. 357, 570 (1981).

[5] Omnibus Consolidated Rescissions and Appropriations Act, 1996, Public Law 104–134, Title II, 110 Stat.1321, 1321–221 (1996).

[6] Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, Public Law 105–78, sec. 212, 111 Stat. 1467, 1495 (1997).

[7] Department of Health and Human Services Appropriations Act, 1999, Public Law 105–277, Title II, sec. 219, 112 Stat. 2681, 2681–363 (1998).

[8] For purposes of this notice of proposed rulemaking, the terms ''grantee'' and ''recipient'' are used interchangeably.

[9] Justice Stevens, the only Justice to find the § 1008 unambiguous, believed it ''plainly'' foreclosed the Secretary's regulations. Stevens dissent at 221.

upheld a lower court injunction prohibiting the directives from taking effect. *Id.*

Almost immediately after taking office, President Clinton issued a memorandum to the Secretary of HHS, directing suspension of the ''gag rule'' and commencement of new rulemaking regarding the Title X program. 58 FR 7455 (Feb. 5, 1993). The Department suspended the 1988 regulations and adopted compliance standards predating the 1988 rules on an interim basis. 58 FR 7462 (Feb. 5, 1993). The Department also sought comment on adopting as final the rules and guidance in effect prior to the 1988 rules. 58 FR 7464 (Feb. 5, 1993). In response to this proposed rulemaking, the Department received 146 comments, and finalized new Title X rules in July of 2000. 65 FR 41270 (July 3, 2000). On that same day, the Department published interpretations relating to the statutory requirement that no funds appropriated under Title X of the Public Health Service Act be used in programs in which abortion is a method of family planning. 65 FR 41281 (July 3, 2000).

The new rules rescinded the 1988 rules prohibiting counseling and referral for abortion. They also eliminated the provisions requiring strict physical and financial separation between Title X projects and abortion related activities, while still requiring that abortion and Title X activities are separated by more than ''mere bookkeeping.'' 65 FR 41270, 41271. Section 59.10 concerning lobbying restrictions was also repealed, while still adhering to long established interpretations of the statute forbidding promotion of abortion through advocacy activities. *Id.* at 41277. Finally, the Department codified the 1981 guidance requiring, upon request of the pregnant patient, nondirective counseling and referral, regarding any option requested: ''(1) prenatal care and delivery; (2) infant care, foster care, or adoption; and (3) pregnancy termination.'' *Id.* at 41279 [42 CFR 59.5(a)(5) (2000 reg)].

In promulgating the 2000 regulations, the Department concluded that revoking the 1988 regulations was within its administrative discretion and that there was no evidence the ''gag rule'' would—or could—work in practice. The Department concluded experience had taught that the rules and policies previous to the 1988 regulations had been accepted by grantees and enabled the program to operate successfully during virtually its entire history. Additionally, the Department relied on the direction from Congress in appropriations riders beginning in 1996 (Pub. L. 104–134), requiring that ''all pregnancy counseling be nondirective,'' believing any referral to a prenatal or other provider when not requested would raise real questions of coercion. The rule also incorporated referrals as a ''logical and appropriate outcome'' of nondirective counseling and consistent with the requirement that the project provide referrals for any medical services not provided by the project [42 CFR 59.5(b)(1)]. *Id.* 41274. For two decades after these rules were finalized (and nearly three decades after they had been in place following the 1988 rule's suspension in 1993), Title X faced no litigation or controversy over these regulations.[10]

In 2018, under a new Administration, the Department proposed new rules again. 83 FR 25502 (June 1, 2018). These rules largely mirrored the 1988 regulations and were finalized in 2019. 84 FR 7714 (March 24, 2019). The Department promulgated the 2019 rules because of its stated view, at that time, that they represented the best interpretation of the statute and provided the most appropriate guidance for compliance with the statutory provisions, including section 1008. While pointing to no direct violations of Title X, associated laws, or the 2000 regulations, the Department believed the 2000 regulations ''fostered an environment of ambiguity surrounding appropriate Title X activities.'' *Id.* at 7721. Therefore, ''bright line rules'' would ameliorate any confusion by grantees and the public.

The Department also cited several conscience protection laws enacted by Congress to support the changes to the 2000 regulations. These laws prohibit public health service grantees from requiring individuals to assist in the performance of health service activities against their religious beliefs or convictions, 42 U.S.C. 300a-7(d), and prohibit discrimination against both individual and institutional providers for their refusal to provide, cover, or refer for abortions. Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 507(d) (2020), Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, sec. 507(d) (2020). The Department concluded in 2019 that the 2000 regulations, if enforced against objecting grantees, would be inconsistent with these statutory protections and dissuade otherwise qualified providers from applying for Title X funds.

The 2019 rules also re-imposed the physical separation provisions of the 1988 rule, as well re-codifying the lobbying restrictions. Additionally, the rule added requirements on grantees and subrecipients regarding compliance with state reporting laws, as well as expanded application and record-keeping requirements. And, with respect to minors, the 2019 rule required providers to document what specific actions were taken to encourage family participation.

As to nondirective counseling and referral for abortion, in recognition of the Congressional direction for nondirective counseling on abortion in yearly appropriations riders, the 2019 rule allowed, but did not require, counseling by grantees, limited to physicians and advanced care providers. *Id.* at 7744. However, the Department believed that the abortion referral requirement was inconsistent with section 1008 and that, though permissible for nearly the entire history of the program, such referrals must be prohibited. *Id.*

Litigation over the 2019 rule immediately ensued. The Department was sued by 23 states, every major medical organization, Title X grantee organizations, and individual grantees. The suits were lodged in multiple district courts and alleged a variety of claims under the Administrative Procedure Act, the Affordable Care Act, and the Constitution. The rule was ultimately upheld by an *en banc* Court of Appeals for the Ninth Circuit and enjoined (only as to the state of Maryland) by a district court in Maryland in a decision upheld by the *en banc* Court of Appeals for the Fourth Circuit. Both court of appeals decisions were issued over substantial dissents.

In *California* v. *Azar,* 950 F.3d 1067 (9th Cir. 2020), the Ninth Circuit relied heavily on *Rust* in upholding the rule. A majority of the *en banc* panel found that the Department ''could'' interpret section 1008 as it did in the 2019 rule, and nothing in subsequent legislation prevented this reading. *Id.* at 1085. The Ninth Circuit upheld the rule against an arbitrary and capricious challenge, stating, ''that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better.'' *Id.* at 1097 (emphasis in original). Conversely, a majority of the Fourth Circuit found the Department's 2019 rule arbitrary and capricious. *Mayor of Baltimore* v. *Azar,* 973 F.3d 258 (4th Cir. 2020). The Fourth Circuit also held the 2019 rule violated the non-directive mandate.[11]

[10] As discussed below, the 2000 rule also fully recognized the statutory conscience right of individual providers to object to counseling and referral for abortions. *Id.* At 41274, 41275.

[11] Both the Ninth and Fourth Circuits also came to opposite results on the validity of the rule under

Losing parties in both cases sought review from the Supreme Court in October of 2020. The Court granted certiorari on February 22, 2021, consolidating the cases. No. 20–429. On March 12, 2021, the parties stipulated to dismiss the cases under Supreme Court Rule 46.1.

III. Public Health Impact as a Result of the 2019 Rules and Reason for this Proposal

The 2019 rule split courts and judges on its approach, its reasonableness, and the interpretation of subsequent legislative provisions. Still, no court questioned the Supreme Court's fundamental holding in *Rust* that section 1008 is ''ambiguous.'' And, while section 1008 may be ambiguous, the public health consequences of the previous Administration's interpretation of the statute are not. The following outlines the effects of the 2019 rule:

- The number of family planning services grantees has dropped precipitously, resulting in an adverse impact on the number of clients served. After the implementation of the 2019 Title X Final Rule, 19 Title X grantees out of 90 total grantees, 231 subrecipients, and 945 service sites immediately withdrew from the Title X program. Overall, the Title X program lost more than 1,000 service sites. Those service sites represented approximately one quarter of all Title X-funded sites in 2019. Title X services are not currently available at all in six states (HI, ME, OR, UT, VT, and WA) and are only available on a very limited basis in six additional states (AK, CT, MA, MN, NH, and NY). California, the single-largest Title X project in the nation (before the 2019 Final Rule) had 128, or 36 percent, of its Title X service sites withdraw from the program, leaving more than 700,000 patients without access to Title X-funded care. Similarly, in New York, the number of Title X-funded service sites dropped from 174 to just two, leaving more than 328,000 patients without Title X-funded care. All Planned Parenthood affiliates—which in 2015 had served 41 percent of all clients at Title X service sites—withdrew from Title X due to the 2019 Final Rule.[12] The withdrawal of numerous grantees, subrecipients, and service sites adversely impacted the number of clients served under the Title X program. With the 2019 Final Rule only being in place for five and a half months, the remaining 71 Title X grantees served 844,083 fewer clients as compared to the previous year, prior to the change in the regulations. Specifically, 3,939,749 clients were served in 2018; 3,095,666 clients were served in 2019, an approximately 22 percent decrease.[13]
- Low-income, uninsured, and racial and ethnic minorities' access to Title X family planning services has decreased, thereby contributing to the increase in health inequities and unmet health needs within these populations. Compared to 2018 Family Planning Annual Report (FPAR) data prior to the implementation of the 2019 Final Rule, in 2019, 573,650 fewer clients under 100 percent of the Federal poverty level (FPL); 139,801 fewer clients between 101 percent to 150 percent FPL; 65,735 fewer clients between 151 percent and 200 percent FPL; and, 30,194 fewer clients between 201 percent to 250 percent FPL received Title X services. This contradicts the purpose and intent of the Title X program, which is to prioritize and increase family planning services to low-income clients. Additionally, 324,776 fewer uninsured clients were served in 2019 compared to 2018. FPAR data also demonstrate that in 2019 compared to 2018, 128,882 fewer African Americans; 50,039 fewer Asians; 6,724 fewer American Indians/Alaska Natives; 7,218 fewer Native Hawaiians/Pacific Islanders; and, 269,569 fewer Hispanics/Latinos received Title X services.[14]
- Provision of critical family planning and related preventive health services has decreased dramatically.[15] The impact of the 2019 Final Rule has been devastating to the hundreds of thousands of Title X clients who have lost access to critical family planning and related preventive health services due to service delivery gaps created by the 2019 Final Rule. More specifically, compared to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008 fewer clients received IUDs. Additionally, 90,386 and 188,920 fewer Papanicolaou (Pap) tests and clinical breast exams respectively were performed in 2019 compared to 2018. Confidential human immunodeficiency virus (HIV) tests decreased by 276,109. Sexually transmitted infection (STI) testing decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis. Furthermore, 71,145 fewer individuals who were pregnant or sought pregnancy were served. As a result of the dramatic decline in Title X services provided, the 2019 Final Rule undermined the mission of the Title X program by helping fewer individuals in planning and spacing births, providing fewer preventive health services, and delivering fewer screenings for STIs. Adolescent services were also adversely affected. In 2019, 151,375 fewer adolescent clients received family planning services and 256,523 fewer women under the age of twenty-five were tested for chlamydia.[16]

The true impact of the 2019 Final Rule in terms of long-term sexual and reproductive health negative sequelae in the lives of hundreds of thousands of low-income clients and clients of color is difficult to quantify. As a result of the decrease in clients able to receive Title X services, it is estimated that the 2019 Final Rule may have led to up to 181,477 unintended pregnancies.[17]

Unintended pregnancies increase the risk for poor maternal and infant outcomes. Individuals having a birth following an unintended pregnancy are less likely to have benefitted from preconception care, to have optimal spacing between births, and to have been aware of their pregnancy early on, which in turn makes it less likely that they would have received prenatal care early in pregnancy.[18] [19] The 2019 Final Rule likely also resulted in additional costs to taxpayers as a result of an increase in unintended pregnancies,

section 1554 of the Affordable Care Act [42 U.S.C. 18114].

[12] (Kaiser Family Foundation, 2020). Current Status of the Title X Network and the Path Forward.

[13] (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from *https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.*

[14] (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from *https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.*

[15] Ibid.

[16] (OPA, 2020). Family Planning Annual Report: 2019 National Summary Report. Accessed on March 9, 2021 from *https://opa.hhs.gov/sites/default/files/2020-09/title-x-fpar-2019-national-summary.pdf.*

[17] Estimating that of the 844,083 fewer clients served by Title X in 2019 compared to 2018, 21.5% of those clients could have experienced an unintended pregnancy as a result of not receiving services. Formula taken from Guttmacher Institute (2017). Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula. Accessed on March 8, 2021 from *https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.*

[18] Jessica D. Gipson, Michael A. Koenig, and Michelle J. Hindin. ''The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature.'' Studies in family planning 39.1 (2008): 18–38. Web.

[19] Power to Decide. Maternal and Infant Health and the Benefits of Birth Control in America. Accessed on March 8, 2020 from *https://powertodecide.org/sites/default/files/resources/supporting-materials/getting-the-facts-straight-chapter-3-maternal-infant-health.pdf.*

preterm and low-birthweight births, STIs, infertility, and cervical cancer.[20]

• OPA has been unable to secure new Title X grantees and service sites to meet the unmet need for family planning services. To meet the unmet need for family planning services nationwide, in Fiscal Year 2019 OPA issued a competitive supplemental funding announcement to existing grantees. Fifty existing grantees were awarded $33.7 million to expand Title X services. However, only 7 states (CO, DE, KY, ND, NM, NV, TX) had a meaningful increase in the number of Title X clinics in their states.

In addition, OPA has been unable to find new grantees to fill most of the gaps the 2019 Final Rule created, including in the six states that lost all Title X-funded services. To address gaps in the Title X service network and increase coverage, a new competitive funding announcement was issued in Fiscal Year 2020 to provide services in unserved or underserved states and communities. The number of applications received was so low (8 eligible applications received) that the resulting grant awards were for less than the total amount of funding available (grant awards for $8.5 million with $20 million available), and were only able to provide services in three states with no or limited Title X services at the time. This demonstrated the negative effects of the 2019 Title X Final Rule on client access to needed family planning and related preventive health services, especially for the priority low-income populations that Title X is mandated to serve.

The realization of a greater pool of grantees, as predicted by the 2019 rule, has not transpired over the course of two grant cycles. As discussed above, OPA was unable to meaningfully expand services nor was it able to find new grantees to fill existing gaps. In fact, the 2019 Final Rule did not increase the pool of grantees and was unable to generate interest in providing Title X services from organizations who had not previously been Title X grantees. This, coupled with the exodus of otherwise qualified grantees, subrecipients and service sites that left the network due to their opposition to the 2019 Final Rule, led to great difficulty in awarding appropriated funds as intended by Congress.

• The 2019 Final Rule is contrary to the CDC and OPA's Quality Family Planning (QFP) Guidelines. In April 2014 (with updates in 2015 and 2017), *Providing Quality Family Planning Services: Recommendations from Centers for Disease Control and Prevention and the US Office of Population Affairs* (QFP),[21] was published as a CDC Morbidity and Mortality Weekly Report (MMWR) Recommendations and Reports. The QFP, developed jointly by the Centers for Disease Control and Prevention (CDC) and the HHS Office of Population Affairs (OPA), provides recommendations for use by all reproductive health and primary care providers with patients who are in need of services related to preventing or for achieving pregnancy. The QFP are scientific and evidence-based recommendations that integrate and fill gaps in existing guidelines for the family planning settings. QFP recommendations are based on a rigorous, systematic, transparent review of the evidence and with input from a broad range of clinical experts, OPA, and CDC. The QFP references numerous other clinical guidelines that are published by Federal agencies, as well as guidelines released by professional medical associations.

These guidelines were developed over a three-year period through the CDC's Division of Reproductive Health (DRH) and OPA, in consultation with a wide range of experts and key stakeholders. These guidelines have been the undisputed standard in reproductive healthcare ever since. QFP recommendations support all providers in delivering quality family planning services and define family planning services within a broader context of preventive services, to improve health outcomes for women, men, and their (future) children.

The client centered approach adopted in the QFP requires pregnancy tests to be ''followed by a discussion of options and appropriate referrals.'' *Id.* at 14 Further, counseling and referral are to be provided, ''at the request of the client,'' in accordance with recommendations from professional medical organizations. Though formally adopted as a QFP recommendation in 2014, appropriate referrals with nondirective counseling have been the practice and implicit standard of care in Title X programs for essentially its entire history, including in early guidelines and later when expressly incorporated in the 2000 regulations.

The 2019 rule abandoned this client centered approach over the objection of every major medical organization without any countervailing public health rationale. Moreover, the 2019 rule required prenatal referral even over the objection of the patient. For the reasons discussed above, that approach cannot be squared with well-accepted public health principles.

• The 2019 Final Rule increased compliance and oversight costs, with no discernible benefit. The 1988 rules requiring strict physical and financial separation requirements, were based, in part, on two governmental reports finding minor compliance issues with grantees and recommended only more specific guidance, not a substantial reworking of the regulations. *See, e.g.,* Comp. Gen. Rep. No GAO/HARD–HRD–82–106 (1982), at 14–15; 65 FR 41270, 41272. While those reports found some confusion among grantees around section 1008, ''GAO found no evidence that Title X funds had been used for abortions or to advise clients to have abortions.'' More importantly, in the decades between 1993 and the 2019 rule, and as evidenced by the silence of the 2019 final rule on this issue, legally required audits, regular site visits, and other oversight of grantees have found no diversion of grant funds that would justify the greatly increased compliance and oversight costs the 2019 rule required.

The 2019 rule's separation requirements also claimed to be addressing questions of ''fungibility'' and a concern that Title X funds might be ''intentionally or unintentionally'' co-mingling with activities not allowed under the statute. 84 FR at 7716. As noted, close oversight for decades under the 2000 rules uncovered no misallocation of Title X funds by grantees. Moreover, courts have long since held that governments cannot restrict access to funds for one activity simply because it may ''free up'' funds for another activity. *See Planned Parenthood of Cent. & N. Arizona* v. *Arizona,* 718 F.2d 938, 945 (9th Cir 1983) (concluding ''as a matter of law, the freeing-up theory cannot justify withdrawing all state funds from otherwise eligible entities merely because they engage in abortion-related activities disfavored by the state''); *see also Agency for Int'l Dev.* v. *Alliance for Open Soc'y Int'l, Inc.,* 570 U.S. 205, 220 (2013) (''[I]f the Government's argument [that fungibility is sufficient for prohibition] were correct, *League of Women Voters* would have come out differently, and much of the reasoning of *Regan* and *Rust* would have been beside the point''). Because of the 2019

[20] Kaiser Family Foundation. *https://www.kff.org/womens-health-policy/issue-brief/data-note-impact-of-new-title-x-regulations-on-network-participation/*

[21] CDC. Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from *https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.*

rule, appropriations that would otherwise be used to carry out the purposes of the Title X program, providing a broad range of family planning services to individuals (including confidential services to minors), are now being diverted to increased infrastructure costs resulting from the separation requirement as well as the micro-level monitoring and reporting now required of grantees. None of these burdensome additional requirements provide discernible compliance benefits, particularly not to public health. As many commenters and at least one court emphasized, the 2019 rule was a solution in search of a problem, a solution whose severe public health consequences caused much greater problems.

The Department also recognizes Congress has passed several laws protecting the conscience rights of providers, particularly in the area of abortion. For example, in promulgating the 2000 Title X rules, the Department affirmed: ''under 42 U.S.C. 300a–7(d), grantees may not require individual employees who have such objections [to abortion] to provide such counseling.'' 65 FR 41270, 41274 (July 3, 2000). Since 2005 Congress has also annually enacted an appropriations rider which extends non-discrimination protections to other ''health care entities'' who refuse to counsel or refer for abortion. *See, e.g.,* Consolidated Appropriations Act, 2021, Public Law 116–260, Div. H, section 507(d) (2020). Under these statutes, objecting providers or Title X grantees are not required to counsel or refer for abortions.[22] However, such protections for objecting providers and grantees should not prohibit willing providers and grantees from providing information in accordance with the ethical codes of major medical organizations.

Ultimately, continued enforcement of the 2019 rule raises the possibility of a two-tiered healthcare system in which those with insurance and full access to healthcare receive full medical information and referrals, while low-income populations with fewer opportunities for care are relegated to inferior access. Given that so many individuals depend on the Title X program as their primary source of healthcare, this situation creates a widespread public health concern. The 2019 rule is not in the best interest of public health.

IV. Proposed Rules

For nearly 50 years without interruption, Title X program grants have been administered against the backdrop of counseling and referral for appropriate medical care, including referral for abortion. Family planning is widely considered one of the most important public health achievements of the 20th Century.[23] As the only Federal program exclusively dedicated to providing contraceptive services, Title X has been imperative to that success.

For five decades, Title X family planning clinics have played a critical role in ensuring access to a broad range of family planning and related preventive health services for millions of low-income or uninsured individuals and others. [24] Over the 50 years of the Title X program, Title X clinics have served more than 190 million clients: 182.2 million women, 8.1 million men, comprising 139.5 million adults and 50.8 million adolescents, across 50 states, the District of Columbia, and eight U.S. territories and freely associated states. Title X providers offered clients a broad range of effective and medically safe contraceptive methods approved by the U.S. Food and Drug Administration. Title X-funded sexually transmitted infection (STI) and human immunodeficiency virus (HIV) screening services prevented transmission and adverse health consequences. Over the 50 years of the Title X program, Title X clinics also performed 34.1 million chlamydia tests, 18.3 million HIV tests, 37 million Papanicolaou tests, and 42 million clinical breast exams.

Given the previous success of the program, the large negative public health consequences of maintaining the 2019 rules, the substantial compliance costs for grantees, and the lack of tangible benefits, the Department proposes revoking the 2019 Title X regulations. As has been clearly borne out by case law and history, the Department has the discretion to make this determination and it is in the interest of public health.

The Department is also concerned that some state policies restricting eligible subrecipients unnecessarily interfere with beneficiaries' access to the most accessible and qualified providers. These state restrictions are not always related to the subrecipients' ability to effectively deliver Title X services, but rather are sometimes based either on the non-Title X activities of the providers or because they are a certain type of provider. However, providers with a reproductive health focus often provide a broader range of contraceptive methods on-site and therefore may reduce additional barriers to accessing services. Moreover, denying participation by family planning providers that can provide effective services has resulted in populations in certain geographic areas being left without Title X providers for an extended period of time.[25] And, while many otherwise qualified providers are willing and can provide effective Title X services, some lack the administrative capacity to directly apply for and manage a Title X grant.

The Department believes that these state restrictions on subrecipient eligibility unrelated to the ability to deliver Title X services undermine the mission of the program to ensure widely available access to services by the most qualified providers. Therefore, the Department invites comment on ways in which it can ensure that Title X projects do not undermine the program's mission by excluding otherwise qualified providers as subrecipients.

In place of the 2019 Title X regulations, the Department proposes to largely readopt the 2000 regulations (65 FR 41270) with several revisions aimed at ensuring access to equitable, affordable, client-centered, quality family planning services. Advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality, is a priority for OPA and the Title X program. By focusing on advancing equity in the Title X program, we can create opportunities for the improvement of communities that have been historically underserved, which benefits everyone. Additionally, given the success of the *Providing Quality Family Planning Services* guidelines published in 2014,[26] the Department is

[22] This has been the consistent position of the Department since 2000. See 65 FR at 41274 (in response to comments on individual objections to providing abortion counseling or referral, Department stating: ''under 42 U.S.C. 300a–7(d), grantees may not require individual employees who have such objections to provide such counseling.'').

[23] Centers. for Disease Control & Prevention, *Achievements in Public Health, 1900–1999: Family Planning,* 48 Morbidity & Mortality Weekly Reports No. 47, 1073–80 (Dec. 3, 1999), *https://www.cdc.gov/mmwr/preview/mmwrhtml/mm4847a1.htm.*

[24] OPA. Title X: Celebrating 50 Years of Title X Service Delivery. Accessed on March 8, 2021 from *https://opa.hhs.gov/sites/default/files/2020-11/title-x-50-years-infographic.pdf.*

[25] Carter, M.W., Gavin, L., Zapata, L.B., Bornstein, M., Mautone-Smith, N., & Moskosky, S.B. (2016). Four aspects of the scope and quality of family planning services in U.S. publicly funded health centers: Results from a survey of health center administrators. Contraception. doi:10.1016/j.contraception.2016.04.009.

[26] CDC. Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from *https://opa.hhs.gov/grant-*

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proposing to incorporate into regulations several of the QFP's recommendations. Based on experience, the Department is also proposing some provisions it believes will make the program function more effectively, efficiently and consistently for all.

The Department proposes revising the 2019 Title X Final Rule through notice and comment rulemaking, by readopting the 2000 regulations with revisions that will enhance the Title X program and its family planning services, including family planning services provided using telemedicine, for the future. This will remove the 2019 Final Rule requirements for strict physical and financial separation, allow Title X providers to provide nondirective options counseling, and allow Title X providers to refer their patients for all family planning related services desired by the client, including abortion services. In addition, this will allow for several revisions that are needed to strengthen the program and ensure access to equitable, affordable, client-centered, trauma-informed quality family planning services for all clients, especially for low-income clients. At the same time, the proposed rule will retain the longstanding prohibition on directly promoting or performing abortion that follows from Section 1008's text and subsequent appropriations enactments. And as indicated above, individuals and grantees with conscience objections will not be required to follow the proposed rule's requirements regarding abortion counseling and referral.

For all the above reasons, the Department proposes to revise the regulations that govern the Title X family planning services program by readopting the 2000 regulations (65 FR 41270), with several modifications. The proposed revisions to the 2000 regulations and rationale for each are listed below:

A. Section 59.2 Definitions

The Department proposes to revise § 59.2 to include a modified definition of family planning. The definition of family planning services included in the 2019 Final Rule did not align with the widely accepted definition. The definition of family planning services should be consistent with the Title X statutory requirements and reflect the widely-recognized definition that is included in *Providing Quality Family Planning Services: Recommendations of CDC and the U.S. Office of Population Affairs,*[27] which has been used historically by OPA when implementing the program prior to 2019. Under the proposed regulations, ''family planning services'' are defined as including a broad range of medically approved contraceptive services, which includes FDA-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

The Department also proposes to add definitions for terms used throughout the revised regulations to provide clarity. The newly proposed definitions include adolescent-friendly health services,[28] client-centered care,[29] health equity,[30] inclusivity,[31] quality [32] healthcare, service site, and trauma-informed.[33]

The proposed definition for ''service site'' is adapted from previous Title X Family Planning Guidelines that implemented the 2000 regulations, the 2014 *Program Requirements for Title X Funded Family Planning Projects* (hereafter ''2014 Title X Program Requirements'').[34] ''Service site'' is defined as a clinic or other location where Title X services are provided to clients. The Title X grantees and/or their subrecipients may have services sites. The proposed definition of service site will assist Title X grantees in more accurately reporting data on their subrecipient and service sites and will eliminate confusion in the OPA Title X clinic locator database.

All other proposed definitions are used by Federal Government agencies or major medical associations, and include:

Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.[35]

Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.[36]

Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.[37]

Health equity is achieved when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.[38]

Inclusivity ensures that all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.[39]

programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.

[27] CDC. Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from *https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.*

[28] World Health Organization. Quality Assessment Guidebook. A guide to assessing health services for adolescent clients. Geneva, World Health Organization, 2009. Accessed on March 8, 2021 from *https://apps.who.int/iris/handle/10665/44240.*

[29] CDC. Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from *https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.*

[30] CDC. Health Equity. Accessed on March 12, 2021 from *https://www.cdc.gov/chronicdisease/healthequity/index.htm.*

[31] White House. Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Accessed on March 8, 2021 from *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.*

[32] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Accessed on March 8, 2021 from *https://www.ncbi.nlm.nih.gov/books/NBK222274/.*

[33] SAMHSA. SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach. Accessed on March 8, 2021 from *https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf.*

[34] OPA. 2014 Program Requirements for Title X Funded Family Planning Projects. Accessed on March 8, 2021 from *https://www.nationalfamilyplanning.org/document.doc?id=1462.*

[35] World Health Organization. Quality Assessment Guidebook. A guide to assessing health services for adolescent clients. Geneva, World Health Organization, 2009. Accessed on March 8, 2021 from *https://apps.who.int/iris/handle/10665/44240.*

[36] CDC. Providing Quality Family Planning Services—Recommendations from CDC and the U.S. Office of Population Affairs. Accessed on March 8, 2021 from *https://opa.hhs.gov/grant-programs/title-x-service-grants/about-title-x-service-grants/quality-family-planning.*

[37] Office of Minority Health. What is Cultural and Linguistic Competence? Accessed on March 8, 2021 from *https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=1&lvlid=6.*

[38] CDC. Health Equity. Accessed on March 12, 2021 from *https://www.cdc.gov/chronicdisease/healthequity/index.htm.*

[39] White House. Executive Order on Advancing Racial Equity and Support for Underserved

Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.[40]

Trauma-informed is a program, organization, or system that realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.[41]

The Department also proposes a technical corrections to § 59.2 to replace ''grantee'' with ''recipient'' in the regulatory text to align with the way the term is used in Federal and HHS regulations.

B. Section 59.5 What requirements must be met by a family planning project?

The Department proposes revising § 59.5(a)(1) to define what constitutes a broad range of acceptable and effective family planning methods and services. The proposed revision revises the 2000 regulations by removing the existing ambiguity and defining what constitutes a broad range of acceptable and effective family planning methods and services. The revised definition of the broad range of methods and services is aligned with the definition used in practice/policy guidance. Moreover, the same definition is included in CDC and OPA's *Recommendations for Providing Quality Family Planning Services*.[42] This revision will result in increased equitable access to a broad range of family planning methods and services to all Title X clients and more clarity in defining those services.

The Department proposes revising § 59.5(a)(1) to require service sites that do not offer a broad range of family planning methods and services on-site to provide clients with a referral for where they can access the broad range and ensure, when feasible, that the referral provided does not unduly limit client access to services, such as excessive distance or travel time to the referral location or referral to services that are cost-prohibitive for the client. While an organization that offers only a single method of family planning may participate as part of a Title X project as long as the entire project offers a broad range of family planning services, offering only a single method of family planning could unduly limit Title X clients, especially low-income clients, by reducing access to a client's method of choice. The Department proposes revising the 2000 regulations to require sites that do not offer the broad range of methods on-site to be able to provide clients with a referral to a provider who does offer the client's method of choice. In addition, the referral provided must be client-centered and not unduly limit access to the client's method of choice. This revision will help to improve access to client-centered services.

The Department proposes to revise § 59.5(a)(3) so that family planning services are required to be client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and ensure equitable and quality service delivery consistent with nationally recognized standards of care. This revision to the 2000 regulations is aimed at increasing access and ensuring equity in all services provided, which is especially important for the Title X program that prioritizes services for low-income clients. Including within the regulation a specific focus on services that are client-centered, culturally and linguistically appropriate, inclusive, trauma-informed, and ensure equitable and quality service delivery will result in improved services provided to clients. These new terms are defined in the proposed regulation under § 59.2, and the added definitions were derived from existing definitions in use by the Federal Government or major medical associations.

The Department proposes revising § 59.5(a)(8) to include widely accepted practices on grant billing practices that were included in previous Title X Family Planning Guidelines. These revisions incorporate language that was included in the 2014 Title X Program Requirements. The 2014 Title X Program Requirements were developed to assist grantees in understanding and implementing the family planning services grants. The 2014 Title X Program Requirements described the various requirements applicable to the Title X program, as set out in the Title X statute and implementing regulations, and in other applicable Federal statutes, regulations, and policies. These billing practices, which are widely accepted in the Title X community, indicate that: (1) Family income should be assessed before determining whether copayments or additional fees are charged; and (2) insured clients whose family income is at or below 250% FPL should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied. These revisions address areas of confusion for grantees prior to the 2014 Title X Program Requirements that were clarified in that document.

The Department proposes adding § 59.5(a)(9) to ensure grantee income verification policies align with the mission of Title X services being prioritized for low-income clients. This addition aims to address an area of common confusion among Title X grantees, which has resulted, in some instances, in a burden being placed on low-income clients. First, a requirement is added (using text from the previous 2014 Title X Program Requirements) to indicate that grantees should take reasonable measures to verify client income. In addition, a new requirement is added to use client self-reported income if the income cannot be verified after reasonable attempts. Without this additional statement, several Title X grantees have established policies to charge full price for services following unsuccessful attempts to verify income, even when the self-reported income is below 250% of the Federal poverty level (FPL) and would have otherwise qualified for no or reduced cost services. This proposed revision will greatly improve accessibility and affordability of services for low-income clients consistently across all Title X grantees.

The Department proposes adding § 59.5(a)(12) to retain some, but not all, language from the 2019 Final Rule on notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking. The notification and reporting requirements are important for Title X providers as mandatory reporters under state laws and protect Title X clients. In addition, this regulation formalizes requirements contained in an annual appropriations rider related to Title X that Congress has included since FY 1999, requiring that, ''[n]otwithstanding any other provision of law, no provider of services under Title X of the PHS Act shall be exempt from any State law requiring notification or the reporting of child abuse, child molestation, sexual abuse, rape, or incest.''

The Department proposes adding § 59.5(a)(13) to describe requirements

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Communities Through the Federal Government. Accessed on March 8, 2021 from *https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/*.

[40] Institute of Medicine. Crossing the Quality Chasm: A New Health System for the 21st Century. Accessed on March 8, 2021 from *https://www.ncbi.nlm.nih.gov/books/NBK222274/*.

[41] SAMHSA. SAMHSA's Concept of Trauma and Guidance for a Trauma-Informed Approach. Accessed on March 8, 2021 from *https://ncsacw.samhsa.gov/userfiles/files/SAMHSA_Trauma.pdf*.

[42] CDC (2014). Providing Quality Family Planning Services, Recommendations of CDC and the U.S. Office of Population Affairs. MMWR, 63(4).

related to subrecipient monitoring and reporting. This addition requires Title X grantees to report on the subrecipients and referral agencies involved in their Title X projects, and to provide their plan for oversight and monitoring of their subrecipients in grantee reports. The regulation no longer requires grantees to report detailed information about each subrecipient and referral agency such as location and specific expertise, which will reduce the increased reporting burden required by the 2019 Final Rule.

The Department proposes revising § 59.5(b)(1) to acknowledge that consultation for medical services related to family planning can be provided by healthcare providers beyond the physician. The proposed revision acknowledges that consultation for healthcare services related to family planning may be by a physician, but may also be by other healthcare providers, including physician assistants and nurse practitioners.

The Department proposes revising § 59.5(b)(3)(iii) to reflect the desire to engage diverse individuals to make services accessible. This revision adds language to clarify the intent at engaging diverse individuals to ensure access to equitable, affordable, client-centered, quality family planning services.

The Department proposes revising § 59.5(b)(8) to add language to the existing 2000 regulation text to include primary healthcare providers in the list of referrals and to state that referrals are to be to providers in close proximity when feasible to the Title X site in order to promote access to services and provide a seamless continuum of care.

The Department also proposes including several technical corrections to § 59.5. The technical correction proposed in §§ 59.5(a)(4) and 59.6(b)(2) replaces the word ''handicapped condition'' with ''disability'' in both sections in order to avoid negative connotations and correct outdated terminology. The technical correction proposed to § 59.5(a)(5) replaces the word ''women'' with ''client'', and the technical correction proposed to § 59.5(a)(6) and (7) replaces the word ''persons'' with ''clients'' to use inclusive language. The technical correction proposed to § 59.5(a)(11) replaces the term ''sub-grantees'' with ''subrecipients''. The technical correction proposed to § 59.5(b)(3) clarifies that focus of this section is on community education, participation, and engagement, and should not be confused with the Information and Education Advisory Committee requirement under § 59.6.

C. Section 59.6 What procedures apply to ensure the suitability of informational and educational material?

The Department proposes deleting prior § 59.5(a)(11) related to the Advisory Committee and consolidating with § 59.6; and revising § 59.6 to clarify intent and remove areas of confusion for grantees regarding the Advisory Committee and other miscellaneous other provisions. The 2000 regulations included information about the Information & Education Advisory Committee in two sections (§§ 59.5(a)(11) and 59.6, which was confusing to Title X grantees. The result is that this revision consolidates all of the Advisory Committee information in one place, under section § 59.6.

In addition, the Department is proposing several minor revisions to clarify that the regulation applies to both print and electronic materials, that the upper limit on council members should be determined by the grantee, that the factors to be considered for broad representation on the Advisory Committee match the definition of inclusivity earlier in the regulation, and that materials will be reviewed for medical accuracy, cultural and linguistic appropriateness, and inclusivity and to ensure they are trauma-informed.

D. Section 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

The Department proposes enabling the Department to consider the ability of the applicant to advance health equity when awarding grant funds. Advancing health equity is critical to the mission of the Title X program. Adding this additional criterion to the 2000 regulations brings the total number of criteria from seven to eight.

E. Section 59.8 How is a grant awarded?

The Department proposes a technical correction to revise § 59.8 to change ''project period'' to ''anticipated period'' since HHS is in the process of adopting revised definition and project period will no longer be used.

F. Section 59.10 Confidentiality.

The Department proposes revising § 59.10 to include a widely accepted practice related to client confidentiality. This proposed revision will add a widely accepted practice in the Title X community that had been previously included in the 2014 Title X Program Requirements, indicating that reasonable efforts must be made to collect charges without jeopardizing client confidentiality. The Department believes that the Title X program will be strengthened by including this clarification within the revised 2000 regulations.

In addition, the Department proposes adding a requirement that grantees must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client. Since state and local laws may vary across jurisdictions (*e.g.,* some are likely to result in notification to the policyholder that the client has received services, others provide for an ''opt out'' process whereby the client can elect that such a notification will not be made), this addition will ensure that the client understands the implications for using their insurance and the options available for them to maintain confidentiality.

G. Section 59.11 Additional Conditions

The Department proposes revising § 59.11 to add ''during'' the period of the award to allow for imposition of additional conditions, during the period of award in addition to ''prior to and at the time of any award'', under circumstances where recipient performance or organizational risk change, *e.g.* if a recipient is failing to perform we may impose new conditions mid-award to require corrective action per 45 CFR 75.207.

H. Section 59.12 What other HHS regulations apply to grants under this subpart?

The Department proposed a technical correction to § 59.12 to update the regulations that apply to 42 CFR part 59, subpart A. The proposal includes a reference to 45 CFR part 87 (''Equal Treatment for Faith-based Organizations'') on the list of regulations that apply to the Title X family planning services program.

V. Regulatory Impact Analyses

A. Introduction

HHS has examined the impacts of the proposed rule under Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, Executive Order 13132 on Federalism, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct HHS to assess all costs and benefits of available regulatory alternatives and, when regulation is

necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). HHS believes that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866 because it would not result in annual effects in excess of $100 million.

The Regulatory Flexibility Act requires HHS to analyze regulatory options that would minimize any significant impact of a rule on small entities. The proposed rule, if finalized, would lessen administrative burdens for grantees of all sizes. Therefore, the Secretary certifies this proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 605.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) (2 U.S.C. 1532) requires HHS to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirement costs on State and local governments or has federalism implications. The proposed rule will not have a significant impact on state funds as, by law, project grants must be funded with at least 90 percent Federal funds. 42 U.S.C. 300a–4(a). The Department has determined that this proposed rule does not impose such costs or have any federalism implications. The Department expects that while some states may not support the policies contained in this proposed rule, many states and local health departments will support the policies contained in this proposed rule, and that it will increase participation by states (many of who dropped out under the 2019 rule).

B. Summary of Costs, Benefits and Transfers

This proposed rule would revise the 2019 Final Rule by readopting the 2000 regulations, with several modifications, and returning the program to the compliance regime as it existed prior to the 2019 rule's implementation. The proposed approach would allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

We predict that this proposed rule would increase the number of grantees receiving Title X funds. In turn, the additional service sites supported by funding would result in additional clients served under the program. These clients receive access to contraception, public health screening including clinical breast exams and Papanicolau (Pap) testing, and testing for sexually transmitted infections. These services result in a reduction in unintended pregnancy, earlier detection of breast and cervical cancer, and earlier detection of sexually transmitted infections including chlamydia, gonorrhea, syphilis, and human immunodeficiency virus (HIV). This screening and testing can result in significant cost savings from earlier treatment and other interventions. This proposed rule would also increase the diversity of grantees receiving funds, including geographic diversity to states that do not currently have a Title X grantee.

The proposed rule would also focus grantees on providing services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery. This focus is especially important for the Title X program that prioritizes services for low-income clients.

This regulatory impact analysis reports the activity occurring at Title X funded sites to provide policymakers with this information. However, the direct impact within the program does not account for services that continue to be provided at sites not receiving Title X funding, filling the gap left by providers that withdrew from the program following the restrictions placed on funding included in the 2019 Final Rule.

C. Preliminary Economic Analysis of Impacts

a. Background

The Title X National Family Planning Program, administered by the U.S. Department of Health and Human Services (HHS), Office of Population Affairs (OPA), is the only Federal program dedicated solely to supporting the delivery of family planning and related preventive healthcare. The program is designed to provide ''a broad range of acceptable and effective family planning methods and services (including natural family planning methods, infertility services, and services for adolescents)'' with priority given to persons from low-income families. In addition to offering these methods and services on a voluntary and confidential basis, Title X-funded service sites provide contraceptive education and counseling; breast and cervical cancer screening; sexually transmitted infections (STIs) and HIV testing, referral, and prevention education; and pregnancy diagnosis and counseling. The program is implemented through competitively awarded grants to state and local public health departments and family planning, community health, and other private nonprofit agencies. In fiscal year 2021, the Title X program received approximately $286.5 million in discretionary Federal Title X funding.

On March 4, 2019, HHS published a final rule to ''prohibit family planning projects from using Title X funds to encourage, promote, provide, refer for, or advocate for abortion as a method of family planning; require assurances of compliance; eliminate the requirement that Title X projects provide abortion counseling and referral; require physical and financial separation of Title X activities from those which are prohibited under section 1008; provide clarification on the appropriate use of funds in regard to the building of infrastructure, and require additional reporting burden from grantees.''

b. Market Failure or Social Purpose Requiring Federal Regulatory Action

The regulatory impact analysis associated with the 2019 Final Rule predicted that the additional restrictions on grantees would result in ''an expanded number of entities interested in participating in Title X.'' Further, the analysis suggested the 2019 Final Rule would result in ''enhanced patient service and care.'' Contrary to these predictions, during the initial period of the 2019 Final Rule's implementation, the policy appears to have had the opposite effect. As we describe in greater detail in the Baseline Section, the restrictions included in the 2019 Final Rule are associated with a substantial reduction in the number of Title X grantees, subrecipients, and service sites, resulting in a

corresponding reduction in total clients served. This is particularly troubling, since the Title X program serves a low-income population that is particularly vulnerable to losing access to these services. This proposed rule is needed to improve the functioning of Government and the effectiveness of the Title X program.

c. Purpose of the Proposed Rule

This proposed rule would revise the regulations that govern the Title X family planning services program by revoking the 2019 Final Rule and readopting the 2000 regulations with several modifications. The proposed approach would allow the Title X program grantees, subrecipients, and service sites to have a greater impact on public health than under the current regulatory approach.

d. Baseline Conditions and Impacts Attributable to the Proposed Rule

We adopt a baseline that assumes the requirements of the 2019 Final Rule remain in place over the period of our analysis. To characterize the real-world impact of the Title X program under this regulatory approach, we develop an annual forecast of grantees, subrecipients, service sites, and total clients served. The key inputs to our forecast are historical data on Title X service grantees. For fiscal years 2016–2019, this information is summarized in the 2019 Title X Family Planning Annual Report. We supplement this information with unpublished preliminary estimates of the impact for fiscal year 2020. Table D1 summarizes these data.

TABLE D1—TITLE X SERVICE GRANTEES

Year	2016	2017	2018	2019	2020
Grantees	91	89	99	100	73
Subrecipients	1,117	1,091	1,128	1,060	803
Service Sites	3,898	3,858	3,954	3,825	2,682
Clients Served	4,007,552	4,004,246	3,939,749	3,095,666	1,536,744

Source: Title X Family Planning Annual Report, 2019: Exhibit A–2a, and unpublished preliminary estimates for FY2020.

The data for fiscal years 2016–2019 included all grantees, subrecipients, and service sites operating at any time during the year. The adoption of the 2019 Title X Final Rule occurred mid-year in 2019. Following this regulation, 19 grantees, 231 subrecipients, and 945 service sites withdrew from the Title X program. The reduced number of grantees, subrecipients, services sites, and clients served observed in 2019 and 2020 cannot be explained by a reduction in discretionary funding for the program, which has remained constant at $286.5 million throughout this time period. Since the 2019 figure includes clients served by these service sites for about half of the year, adopting 3.1 million clients served as an annual forecast would likely overstate activity in the program under the current regulations. Indeed, preliminary figures for FY2020 indicate that only about 1.5 million clients were served. However, this figure likely represents an underestimate for a typical year of the program under the current regulations since services were likely disrupted by the ongoing public health emergency.

As our primary estimate, we adopt 2,512,066 clients served as the baseline annual impact of Title X under the policies of the 2019 Final Rule. This 2.5 million corresponds to the number of clients served in 2019 among remaining grantees as of March 2021. For comparison, this primary estimate represents a 37% reduction in clients served compared to the average of clients served from 2016 to 2018. In the Uncertainty and Sensitivity Analysis Section, we adopt the 1.5 million client figure as a lower-bound estimate, and 3.1 million clients as an upper-bound estimate of the annual program impact under the baseline.

Table D2 summarizes our baseline forecast for the same categories of historical data presented in Table D1. We adopt the current count for grantees, subrecipients, and services sites. We assume these figures will be constant over time horizon of this analysis.

TABLE D2—BASELINE FORECAST OF TITLE X SERVICES

Baseline forecast	Annual
Grantees	73
Subrecipients	803
Service Sites	2,682
Clients Served	2,512,066

In addition to the reduction in grantees, subrecipients, service sites, and total client served, we note that six states currently have no Title X services, including HI, ME, OR, UT, VT, and WA. There are six additional states that have limited Title X services, including AK, CT, MA, MN, NH, and NY.[43]

In line with the reduction in clients served under the 2019 Final Rule, data also reveal a significant drop in services provided For example, when comparing 2019 figures to 2018, 225,688 fewer clients received oral contraceptives; 49,803 fewer clients received hormonal implants; and 86,008 fewer clients received intrauterine devices (IUDs). For oral contraceptives and IUDs, this was a 27% reduction; and for hormonal implants, a 21% reduction. These percentages are similar in magnitude to the 21% reduction in clients served in 2019 compared to 2018. Additionally, 90,386 and 188,920 fewer Pap tests and clinical breast exams, respectively, were performed in 2019 compared to 2018. Confidential HIV tests decreased by 276,109. Testing for sexually transmitted infections (STIs) decreased by 256,523 for chlamydia, by 625,802 for gonorrhea, and by 77,524 for syphilis.

For our forecast of services provided under our baseline scenario, we adopt the most recent percentage of clients receiving each service in the 2019 Title X Family Planning Annual Report. For example, in 2019, about 23% of female clients received a clinical breast exam. We assume the same share of clients will be served by Title X for screening and sexually transmitted infection testing. Table D3 reports our best estimate of the annual services provided under the baseline scenario. We describe these services in greater detail later in this Section.

TABLE D3—BASELINE TITLE X CANCER SCREENING AND SEXUALLY TRANSMITTED INFECTION TESTING

Year	Annual
Clinical Breast Exams	509,550
Pap Tests	443,087
Chlamydia Test	1,266,508
Gonorrhea Test	1,420,198
Syphilis Test	536,619

[43] As noted earlier, seven states (CO, DE, KY, ND, NM, NV, TX) experienced a meaningful increase in the number of Title X clinics after the 2019 regulatory change.

TABLE D3—BASELINE TITLE X CANCER SCREENING AND SEXUALLY TRANSMITTED INFECTION TESTING—Continued

Year	Annual
Confidential HIV Test	777,536

Source: Calculations based on Title X Family Planning Annual Report, 2019: Exhibits 26 and 29.

We predict that the main effect of the proposed rule would be to return to Title X program impact levels observed prior to the 2019 Final Rule. Our estimates of the long-run equilibrium of grantees, subrecipients, service sites, and total client served are informed by the data from fiscal years 2016–2018, the last three years of data that are unaffected by the drops experienced following the 2019 Final Rule. Specifically, we adopt the average across these three years as our long-run estimates. These averages are 93 grantees, 1,112 subrecipients, 3,903 service sites, and about 4.0 million clients served.

To complete our forecast of the policy scenario, we assume that it will take two years for program participation and clients served to achieve the long-run equilibrium estimates. This two-year phase-in is consistent with a scenario in which most service sites that withdrew from the Title X program have remained open, with some operating at a lower capacity, than they did prior to the 2019 Final Rule. It is also consistent with an expectation that many of the grantees and service sites that withdrew from the program would be able to rejoin if this proposed rule were finalized. In year one, following the effective date of the proposed rule, the number of clients served would increase to about 3.2 million. In year two, this number would increase again to about 4.0 million and remain there for the duration of our analysis. These figures are presented in Table D4. We acknowledge uncertainty in this estimate, and include a discussion in the Uncertainty and Sensitivity Section, below.

TABLE D4—POLICY SCENARIO FORECAST OF TITLE X SERVICE GRANTEES

Year	2022	2023	2024	2025	2026
Grantees	80	86	93	93	93
Subrecipients	906	1,009	1,112	1,112	1,112
Service Sites	3,089	3,496	3,903	3,903	3,903
Clients Served	3,247,958	3,983,849	3,983,849	3,983,849	3,983,849

To characterize the effect of the proposed rule, we compare the policy scenario forecast to the baseline forecast described in the previous section. Table D5 reports the difference between these two scenarios, which represents the net effect of the proposed rule. For example, in year 1 after this rule is effective, the number of clients served would be about 736,000 higher than under the baseline scenario. Approximately 88% of clients served in 2016–2018 are female, and we use this percentage to estimate the increase in clients served by sex under the policy scenario.

TABLE D5—EFFECT OF THE PROPOSED RULE ON TITLE X SERVICES

Year	2022	2023	2024	2025	2026
Increase in Grantees	7	13	20	20	20
Increase in Subrecipients	103	206	309	309	309
Increase in Service Sites	407	814	1,221	1,221	1,221
Increase in Clients Served	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Female	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Male	86,896	173,791	173,791	173,791	173,791

Clients served under the Title X program experience outcomes that include reducing unintended pregnancy through greater access to contraception. The averted unintended pregnancies translate to a reduction in unplanned births, a reduction in abortions, and reduction in miscarriages. Also, Title X clients receive cancer screenings and testing for sexually transmitted infections. These screenings and testing can identify treatable conditions, improving the quality of life and extending the lives of beneficiaries. In the case of sexually transmitted infections, additional testing can reduce the likelihood of further infections and future infertility. This proposed rule would expand service to socioeconomically disadvantaged populations, most of whom are female, low income, and young. We discuss this in greater detail in the Section on Distributional Effects.

To further explore the likely effect of the Title X program on unintended pregnancy, we rely on existing methodology for estimating number of unintended pregnancies prevented each year among U.S. women who depend on publicly funded family planning services.[44] Among this subgroup of women who use any method of contraception, 46 in 1,000 women are expected to experience an unintended pregnancy. This figure can be compared to 296 unintended pregnancies per 1,000 women who are unable to access public family planning services. We apply this estimate of a reduction of 250 unintended pregnancies per 1,000 contraception clients to the number of additional female clients served under the Title X program who adopt any method of contraception.

For year 1, we multiply 735,892 clients by 88% to yield 648,996 clients who are women. Among female clients, approximately 14% indicate they are not using a method of contraception, according to figures in the 2019 Title X Family Planning Annual Report. We reduce the potential number of clients that would potentially reduce the likelihood of an unintended pregnancy by 14% to yield 558,205 clients expected to benefit from a contraceptive method. Approximately 47% of unintended pregnancies result in

[44] Jennifer J. Frost and Lawrence B. Finer (2017). Memo entitled ''Unintended pregnancies prevented by publicly funded family planning services: Summary of results and estimation formula.'' *https://www.guttmacher.org/sites/default/files/pdfs/pubs/Guttmacher-Memo-on-Estimation-of-Unintended-Pregnancies-Prevented-June-2017.pdf.* Accessed on March 14, 2021.

unplanned births, 34% in abortion, and 19% in a miscarriage.[45]

TABLE D6—EFFECT OF THE PROPOSED RULE ON TITLE X-ASSOCIATED CONTRACEPTION

Year	2022	2023	2024	2025	2026
Clients Served	735,892	1,471,783	1,471,783	1,471,783	1,471,783
Women Served	648,996	1,297,992	1,297,992	1,297,992	1,297,992
Women Served Using Contraception	558,205	1,116,411	1,116,411	1,116,411	1,116,411

Unintended and unplanned pregnancies increase the risk for poor maternal and infant outcomes. Women who give birth following an unintended or unplanned pregnancy are less likely to have benefitted from preconception care, to have optimal spacing between births, and to have been aware of their pregnancy early on, which in turn makes it less likely that they would have received prenatal care early in pregnancy.[46] [47]

Title X funding recipients also perform preventive health services such as cervical and breast cancer screening, and testing for sexually transmitted infections, including chlamydia, gonorrhea, syphilis, and HIV. Table D6 presents the effect of the proposed rule on Title X-associated cervical and breast cancer screenings. These figures are calculated by multiplying the number of additional women served by the program in each year by about 23% for clinical breast exams, of which 5% result in a referral for further evaluation; and 20% for Pap testing, of which 13% with a result of atypical squamous cells (ASC) that require further evaluation and possibly treatment, and 1% of which have a high-grade squamous intraepithelial lesion (HSIL)[48] or higher, indicating the presence of a more severe condition.

Clinical breast exams can identify women requiring further evaluation of an abnormal finding. Pap test (or pap smear test) results can indicate viral infections that, when untreated, can turn into cervical cancer. The Pap test results can also detect cervical cancer cells. At a population level, these screenings save lives by helping women identify cancer earlier, and preventing other conditions from developing into cancer.

TABLE D7—EFFECT OF THE PROPOSED RULE ON TITLE X-ASSOCIATED CERVICAL AND BREAST CANCER SCREENING ACTIVITIES

Year	2022	2023	2024	2025	2026
Clinical Breast Exams	149,269	298,538	298,538	298,538	298,538
Referred	7,463	14,927	14,927	14,927	14,927
Pap Tests	129,799	259,598	259,598	259,598	259,598
Tests with ASC or higher	17,304	34,609	34,609	34,609	34,609
Tests with HSIL or higher	195	391	391	391	391

Table D7 presents the effect of the proposed rule on Title X-associated testing for sexually transmitted infections among female clients. These are calculated by adopting estimates that 49% of women are tested for chlamydia; 55% for gonorrhea; 19% for syphilis; and 28% for HIV. Table D6 presents the same information for men. The share of male clients tested for these infections are the following: 61% for chlamydia, 68% for gonorrhea, 39% for syphilis, and 53% for HIV.

TABLE D8—ADDITIONAL WOMEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia	318,008	636,016	636,016	636,016	636,016
Gonorrhea	356,948	713,895	713,895	713,895	713,895
Syphilis	123,309	246,618	246,618	246,618	246,618
Confidential HIV	181,719	363,438	363,438	363,438	363,438

TABLE D9—ADDITIONAL MEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia	53,006	106,013	106,013	106,013	106,013
Gonorrhea	59,089	118,178	118,178	118,178	118,178
Syphilis	33,889	67,779	67,779	67,779	67,779

[45] Jennifer J. Frost, Lori F. Frohwirth, Nakeisha Blades, Mia R. Zolna, Ayana Douglas-Hall, and Jonathan Bearak (2017). ''Publicly Funded Contraceptive Services at U.S. Clinics, 2015. *https://www.guttmacher.org/sites/default/files/report_pdf/publicly_funded_contraceptive_services_2015_3.pdf.* Accessed on March 14, 2021.

[46] Jessica D. Gipson, Michael A. Koenig, and Michelle J. Hindin. ''The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature.'' Studies in family planning 39.1 (2008): 18–38. Web.

[47] Power to Decide. Maternal and Infant Health and the Benefits of Birth Control in America. Accessed on March 8, 2020 from *https://powertodecide.org/sites/default/files/resources/supporting-materials/getting-the-facts-straight-chapter-3-maternal-infant-health.pdf.*

[48] HSIL is the abnormal growth of certain cells on the surface of the cervix.

TABLE D9—ADDITIONAL MEN TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X—Continued

Year	2022	2023	2024	2025	2026
Confidential HIV	46,055	92,109	92,109	92,109	92,109

Table D8 reports the total clients tested for sexually transmitted infections. These tests can identify treatable conditions that can cause discomfort, permanent damage to reproductive systems including infertility, and in certain cases, death. The 2019 Title X Family Planning Annual Report indicates confidential HIV testing identifies a positive case for approximately 0.38% of all HIV tests performed. If the proposed rule is finalized, Title X would be associated with identifying an additional 873 positive cases of HIV. In subsequent years, this number would increase to 1,745. Testing for these sexually transmitted infections can also reduce the likelihood that an individual will spread an infection. In addition to testing, Title X-funded service sites also provide HIV/AIDS prevention education. Pre-exposure prophylaxis (PrEP) has emerged as an effective HIV prevention strategy for individuals who are most at risk, and the inclusion of PrEP in the HIV prevention services provided at Title X sites is becoming an increasingly important method for protecting individuals of all ages from acquiring HIV.

TABLE D10—ADDITIONAL CLIENTS TESTED FOR SEXUALLY TRANSMITTED INFECTIONS UNDER TITLE X

Year	2022	2023	2024	2025	2026
Chlamydia	371,014	742,029	742,029	742,029	742,029
Gonorrhea	416,037	832,074	832,074	832,074	832,074
Syphilis	157,199	314,397	314,397	314,397	314,397
Confidential HIV	227,774	455,547	455,547	455,547	455,547
Positive Test Results	873	1,745	1,745	1,745	1,745

Services of the type provided under Title X likely result in reduced costs to taxpayers as a result of a reduction in unintended pregnancies, pre-term and low-birthweight births, sexually transmitted infections, infertility, and cervical cancer. This report [49] estimates that each dollar spent on these services results in a net Government saving of $7.09. We do not replicate the calculations, but note that they are derived from cost savings associated with averting unintended pregnancy and complications such as pre-term and low birth-weight births. These cost savings are also derived from detecting and treating sexually transmitted infections that would have resulted in more serious outcomes, including infertility, cancer, and death.

In addition to the effects described above, this proposed rule would also enhance the equity and dignity associated with access to family planning services provided by Title X. A recent research brief summarized interviews with 30 women sharing their experiences with contraceptive access, providing suggestive evidence that birth control has an important positive impact on women's lives. Interviewees noted that birth control allowed women to ''to pursue academic and professional goals, achieve financial stability, and maintain their mental and physical health.'' [50] These recent interviews are consistent with the historical experience of the importance of birth control. For example, one econometric study identifies a causal relationship between the introduction and diffusion of the birth control pill and the increase in women enrolling in professional degree programs and increasing the age at first marriage.[51] Title X services help connect women with the free contraception provided by the Affordable Care Act, which allows them to experience these and other positive outcomes associated with access to contraception.

Researchers have identified other economic, social, and health impacts of increased access to family planning, contraception, and treatment. For example, Bailey et al. (2019) finds ''that children born after the introduction of Federal family planning programs were 7 percent less likely to live in poverty and 12 percent less likely to live in households receiving public assistance.'' They perform an additional bounding analysis, which suggests that about two thirds of the estimated gains are due to increases in the incomes of parents.[52] A recent summary discusses other impacts of access to family planning services in the United States and in other countries, which extends beyond women and girls, to their children and wider communities.[53]

The calculations above represent observable metrics of the effect of the Title X program, which is important for evaluating the direct effect of the program. For this reason, the scope of our analysis initially focuses on clients served and services provided by Title X facilities. To properly account for the net effect of the proposed rule when comparing the baseline scenario to the policy scenario, we would need to assess the extent to which clients and services continue to be provided through other channels than Title X funded sites without the proposed rule. As a general matter, the impacts of this proposed rule may include:

- Transfers between grantees and would-be grantees within the Title X program;
- other transfers (for example, if Title X newly funds medical services that would, in the absence of the proposed rule, be provided by charitable

[49] Jennifer J. Frost, Adam Sonfield, Mia R. Zolna, and Lawrence B. Finer (2014). ''Return on Investment: A fuller assessment of the benefits and costs of the US publicly funded family planning program'' Milbank Quarterly 2014 Dec;92(4):696–749.

[50] Rebecca Peters, Sarah Benetar, Brigette Courtot, and Sophia Yin (2019). ''Birth Control is Transformative.'' Urban Institute. *https://www.urban.org/sites/default/files/publication/99912/birth_control_is_transformative_1.pdf.* Accessed April 6, 2021.

[51] Goldin, Claudia and Lawrence F. Katz (2002). ''The power of the pill: Oral contraceptives and women's career and marriage decisions.'' *Journal of Political Economy* 110(4): 730–770.

[52] Bailey, Martha J., Olga Malkova, Zoë M. McLaren (2019). ''Does Access to Family Planning Increase Children's Opportunities? Evidence from the War on Poverty and the Early Years of Title X.'' *Journal of Human Resources* 54:4 pp. 825–856. doi:10.3368/jhr.54.4.1216–8401R1.

[53] Emily Sohn (2020). ''Strengthening society with contraception.'' *Nature* 588, S162–S164.

organizations or other private payers); and

- societal benefits and costs to the extent that the volume or characteristics (such as location, which determines travel costs) of medical services would differ with and without the proposed rule.

As noted earlier in this preamble, all Planned Parenthood affiliates—which, in 2015, served 41 percent of all contraceptive clients at Title X-funded service sites—withdrew from Title X due to the 2019 Final Rule. However, a comparison of Planned Parenthood's two most recent annual financial reports indicates no subsequent decrease in the number of patients served and an increase, from 9.8 million to 10.4 million, in the number of services provided per annum (pre-pandemic).[54] Although such year-to-year comparisons are simplistic and a focus on just one organization (even a prominent one, with extensive activities) has obvious limitations, this evidence may suggest that the Title X program impacts quantified elsewhere in this regulatory impact analysis may largely be associated with transfers. Although there are notable challenges with quantifying the benefit, cost and transfer impacts of the proposed rule, we request comment that might facilitate refinement of the analysis prior to regulatory finalization.

e. Further Discussion of Distributional Effects

The Title X program is designed to provide services with priority given to persons from low-income families. According to the most recent data, 64% of clients have income under 101% of the Federal poverty level; 14% between 101% and 150%; 7% between 151% to 200%; 3% between 201% and 250%; 7% over 250%; and 5% have an unknown or unreported income level. Among program clients, 33% are Hispanic or Latino of all races; 3% are Asian and Not Hispanic or Latino; 22% are Black or African American and Not Hispanic or Latino; 32% are White and Not Hispanic or Latino; and 5% are Other or Unknown and Not Hispanic or Latino; and 4% are Unknown or not Reported. Furthermore, the Title X statutory directive requires Title X projects to provide services for adolescents without required parental consent. This makes Title X a critical source of sexual and reproductive healthcare for young people. In 2019, 2% program clients were younger than 15, and 8% were younger than 18. Additional information about the number and distribution of all family planning clients by age and year are available in Exhibit A–3a of the 2019 Title X Annual Report. The benefits of revoking the 2019 Final Rule would likely accrue roughly in proportion with these income and race and ethnicity figures. The costs of revoking the 2019 Final Rule would likely accrue proportional to the income and other demographics of the general public.

This proposed rule would also likely have important geographic effects. As described in greater detail in the Baseline Section, 6 States currently have no Title X services, and 6 additional states have limited Title X services. This proposed rule would likely result in restoration of services to individuals in these States.

f. Uncertainty and Sensitivity Analysis

All of the major drivers of the quantified effects of this analysis are dependent on our forecast of the baseline number of clients served. We acknowledge the uncertainty in this baseline and have performed a sensitivity analysis to quantify its importance. For our primary baseline, we chose 2.5 million annual clients of Title X services, which corresponds to the number of clients in fiscal year 2019 among remaining grantees. As a sensitivity analysis, we investigate the effect of the proposed rule compared to a baseline with 1.5 million clients, corresponding to preliminary estimates for fiscal year 2020. For comparison, we also looked at the effects using an upper bound of 3.1 million clients served, which is the reported figure for 2019, but which includes 19 grantees, 231 subrecipients, and 945 service sites that withdraw from the Title X program following the 2019 Final Rule.

Table F1 presents the number of clients served under different assumptions of the baseline. We also recalculate the number of clients served for the proposed rule scenario for each of the baseline assumptions. Since the number of clients served in the first year is the midpoint between the baseline and long-run equilibrium figure, the number of clients served in fiscal year 2022 under the proposed rule would be lower for the lower-bound scenario than the primary baseline. Similarly, the number of clients served under the proposed rule would be higher in the upper-bound scenario.

TABLE F1—TITLE X CLIENTS SERVED UNDER DIFFERENT BASELINE ASSUMPTIONS

Year	Baseline	Baseline, LB	Baseline, UB	Proposed rule	Proposed rule, LB	Proposed rule, UB
2022	2,512,066	1,536,744	3,095,666	3,247,958	2,760,297	3,539,758
2023	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849
2024	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849
2025	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849
2026	2,512,066	1,536,744	3,095,666	3,983,849	3,983,849	3,983,849

Table F2 calculates the effect of the proposed rule under different baseline assumptions. These estimates are reported by year, as well as in present value and annualized for the 5-year time horizon of our analysis, applying a 3% and a 7% discount rate. Under the lower-bound baseline scenario, the proposed rule would have about a 66% greater impact on the number of clients served in annualized terms under the primary baseline scenario. Under the upper-bound baseline scenario, the proposed rule would have about a 64% lesser impact.

[54] Please see *https://www.plannedparenthood.org/uploads/filer_public/2e/da/2eda3f50-82aa-4ddb-acce-c2854c4ea80b/2018-2019_annual_report.pdf* and *https://www.plannedparenthood.org/uploads/filer_public/67/30/67305ea1-8da2-4cee-9191-19228c1d6f70/210219-annual-report-2019-2020-web-final.pdf*. The latter report indicates that Planned Parenthood conducted a major fundraising campaign with the 2019 Title X regulatory changes as its key motivating message. If funds are more efficiently gathered and distributed via a program such as Title X than through such private campaigns, the efficiency would represent a cost savings attributable to the proposed rule.

TABLE F2—EFFECT OF THE PROPOSED RULE UNDER DIFFERENT BASELINE ASSUMPTIONS

Year	Proposed rule	Proposed rule, LB	Proposed rule, UB
2022	735,892	1,223,553	444,092
2023	1,471,783	2,447,105	888,183
2024	1,471,783	2,447,105	888,183
2025	1,471,783	2,447,105	888,183
2026	1,471,783	2,447,105	888,183
PDV, 3%	6,025,877	10,019,109	3,636,461
PDV, 7%	5,346,852	8,890,107	3,226,687
Annualized, 3%	1,315,778	2,187,718	794,038
Annualized, 7%	1,304,047	2,168,214	786,959

As discussed earlier, we acknowledge uncertainty in how quickly the Title X program will be able to restore service to levels experienced prior to the drops associated with the 2019 Final Rule. Our primary analysis adopts a two-year phase for grantees, subrecipients, service sites, and clients served to reach our long-run equilibrium estimates. If a large number of service sites have shut down permanently, the assumption of a two-year phase in would likely result in an overestimate of the proposed rule's effect over the time horizon of the analysis. Similarly, if a small number of service sites have shut down, the analysis would tend to underestimate the effect of the proposed rule. Therefore, as a second sensitivity analysis, we present estimates that adopt alternative assumptions about the length of time it will take to reach the long-run equilibrium estimates. Table F3 presents our primary estimates, based on a two-year phase in, estimates without a phase in, and estimates with a 3-year phase in assumption.

TABLE F3—TITLE X CLIENTS WITH DIFFERENT PHASE-IN ASSUMPTIONS

Year	Baseline	Proposed rule, 2-year phase in	Proposed rule, no phase in	Proposed rule, 3-year phase in
2022	2,512,066	3,247,958	3,983,849	3,002,660
2023	2,512,066	3,983,849	3,983,849	3,493,255
2024	2,512,066	3,983,849	3,983,849	3,983,849
2025	2,512,066	3,983,849	3,983,849	3,983,849
2026	2,512,066	3,983,849	3,983,849	3,983,849

Table H4 calculates the effect of the proposed rule with different phase-in assumptions. These estimates are reported by year, as well as in present value and annualized for the 5-year time horizon of our analysis, applying a 3% and a 7% discount rate. Compared to our primary estimates, the assumption of no phase in yields annualized effects of the proposed rule that are about 12% higher. Assuming a 3-year phase in yields annualized effects that are about 12% lower than the primary estimates.

TABLE F4—EFFECT OF THE PROPOSED RULE WITH DIFFERENT PHASE-IN ASSUMPTIONS

Year	Proposed rule, 2-year phase in	Proposed rule, no phase in	Proposed rule, 3-year phase in
2022	735,892	1,471,783	490,594
2023	1,471,783	1,471,783	981,189
2024	1,471,783	1,471,783	1,471,783
2025	1,471,783	1,471,783	1,471,783
2026	1,471,783	1,471,783	1,471,783
PDV, 3%	6,025,877	6,740,335	5,325,293
PDV, 7%	5,346,852	6,034,601	4,689,098
Annualized, 3%	1,315,778	1,471,783	1,162,802
Annualized, 7%	1,304,047	1,471,783	1,143,627

g. Analysis of Regulatory Alternatives to the Proposed Rule

We analyzed two alternatives to the approach under the proposed rule. We considered one option to maintain many elements of the 2019 Final Rule and to impose additional restrictions on grantees. This approach would exacerbate the trends of reduced Title X grantees, subrecipients, service sites, and clients served that we have observed under the 2019 Final Rule. Second, we considered revising the 2019 Final Rule by readopting many elements of the 2000 regulations, but adopting additional flexibilities for grantees and reducing programmatic oversight. However, our experience suggests the compliance regime as it existed prior to the 2019 Final Rule was effective.

VI. Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an

environmental assessment nor an environmental impact statement is required.

VII. Paperwork Reduction Act

This proposed rule contains information collection requirements (ICRs) that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 1. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (PRA) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of the required issues under section 3506(c)(2)(A) of the PRA. The collections of information required by the proposed rule relate to § 59.5 (What requirements must be met by a family planning project?) and § 59.7 (What criteria would the Department of Health and Human Services use to decide which family planning services projects to fund and in what amounts?).

Proposed § 59.4 would require Title X grant applicants to describe how the proposed project would satisfy the regulatory requirements for the Title X program in their applications. All other reporting burden associated with grant applications is already approved via existing *Grants.gov* common forms.

Proposed § 59.5 would require Title X providers to report, in grant applications and in all required reports, information regarding subrecipients and referral agencies and individuals, including a description of the extent of collaboration and a clear explanation of how the grantee would ensure adequate oversight and accountability.

Proposed § 59.5 would also require Title X grantees to provide appropriate documentation or other assurance satisfactory to the Secretary that it has in place and has implemented a plan to comply with all State and local laws requiring notification or reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence, and human trafficking. It would also require Title X grantees to maintain records to demonstrate compliance with the requirements of § 59.5, and make continuation of funding for Title X services contingent upon demonstrating to the Secretary that the criteria have been met.

Burden of Response: The Department is committed to leveraging existing grant, contract, annual reporting, and other Departmental forms where possible, rather than creating additional, separate forms for recipients to sign. We anticipate two separate burdens of response: (1) Assurance of compliance; and (2) documentation of compliance. The burden for the assurance of compliance is the cost of grantee and/or subrecipient staff time to (a) review the assurance language as well as the underlying language related to stated requirements; (b) to review grantee and/or subrecipient policies and procedures or to take other actions to assess grantee and/or subrecipient compliance with the requirements to which the grantee and/or subrecipient is required to assure compliance.

The labor cost would include a lawyer spending an average of 1 hour reviewing all assurances and a medical and health service manager spending an average of one hour reviewing and signing the assurances at each grantee and subrecipient. We estimate the number of grantees and subrecipients at 1060, based on 2019 number of Title X grantees and subrecipients, as represented in Title X FPAR data. The mean hourly wage (not including benefits and overhead) for these occupations is $69.86 per hour for the lawyer and $55.37 per hour for the medical and health service manager. The labor cost is $132,750 in the first year (($69.86 × 1 + $55.37 × 1) × 1060 grantees and subrecipients). We estimate that the cost, in subsequent years, would be $95,700 which would represent an annual allotment of 30 minutes for the lawyer and one hour for the medical and health service manager (($69.86 × 0.5 + $55.37 × 1) × 1060 grantees and subrecipients).

The Department estimates that all recipients and subrecipients will review their organizational policies and procedures or take other actions to self-assess compliance with applicable Title X requirements each year, spending an average of 4 hours doing so. The labor cost is a function of a lawyer spending an average of 2 hours and a medical and health service manager spending an average of 2 hours. The labor cost for self-assessing compliance, such as reviewing policies and procedures, is a total of $265,500 each year (($69.86 × 2 + $55.37 × 2) × 1060 grantees and subrecipients).

The burden for the documentation of compliance is the cost of grantee and/or subrecipient staff time to (a) complete reports regarding information related to subrecipients, referral agencies and individuals involved in the grantee's Title X project.

The labor cost would include a medical and health services manager spending an average of two hours each year to complete reports regarding information related to subrecipients, and referral agencies and individuals involved in the grantee's Title X project at each grantee and subrecipient. The labor cost will be $117,400 each year ($55.37 × 2 hours × 1060 grantees and subrecipients).

TABLE 1—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS OR BURDEN OF RESPONSE IN YEAR ONE/SUBSEQUENT YEARS FOLLOWING PUBLICATION OF THE FINAL RULE

Regulation burden	OMB control No.	Respondents responses	Hourly rate ($)	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)
Assurance of Compliance	0938-New	1060/1060	62.62/62.62	6/5.44	6360/5766	398,250/ 361,200
Documentation of Compliance	0938-New	1060/1060	55.37/55.37	2/2	2120/2120	117,400/ 117,400

TABLE 1—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS OR BURDEN OF RESPONSE IN YEAR ONE/SUBSEQUENT YEARS FOLLOWING PUBLICATION OF THE FINAL RULE—Continued

Regulation burden	OMB control No.	Respondents responses	Hourly rate ($)	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)
Total cost						516,650/ 478,600

Note: The Department asks for public comment on the proposed information collection including what additional benefits may be cited as a result of this proposed rule. Comments regarding the collection of information proposed in this proposed rule must refer to the proposed rule by name and docket number, and must be submitted to both OMB and the Docket Management Facility where indicated under **ADDRESSES** by the date specified under **DATES**. When it issues a final rule, the Department plans to publish in the FEDERAL REGISTER the control numbers assigned by the Office of Management and Budget (OMB). Publication of the control numbers notifies the public that OMB has approved the final rule's information collection requirements under the Paperwork Reduction Act of 1995.

List of Subjects in 42 CFR Part 59

Birth control, Contraception, Family planning, Grant programs, Health facilities, Title X.

Xavier Becerra,

Secretary, Department of Health and Human Services.

PART 59—GRANTS FOR FAMILY PLANNING

For the reasons set out in the preamble, subpart A of part 59 of title 42, Code of Federal Regulations, is hereby proposed to be revised to read as follows:

Subpart A—Project Grants for Family Planning Services

Sec.

Subpart A—Project Grants for Family Planning Services

Authority: 42 U.S.C. 300a–4.

§ 59.1 To what programs do the regulations in this subpart apply?

The regulations of this subpart are applicable to the award of grants under section 1001 of the Public Health Service Act (42 U.S.C. 3200) to assist in the establishment and operation of voluntary family planning projects. These projects shall consist of the educational, comprehensive medical, and social services necessary to aid individuals to determine freely the number and spacing of their children.

§ 59.2 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Adolescent-friendly health services are services that are accessible, acceptable, equitable, appropriate and effective for adolescents.

Client-centered care is respectful of, and responsive to, individual client preferences, needs, and values; client values guide all clinical decisions.

Culturally and linguistically appropriate services are respectful of and responsive to the health beliefs, practices and needs of diverse patients.

Family means a social unit composed of one person, or two or more persons living together, as a household.

Family planning services include a broad range of medically approved contraceptive services, which includes Food and Drug Administration (FDA)-approved contraceptive services and natural family planning methods, for clients who want to prevent pregnancy and space births, pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, sexually transmitted infection (STI) services, and other preconception health services.

Health equity is when every person has the opportunity to attain their full health potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances.

Inclusivity ensures that all people are fully included and can actively participate in and benefit from family planning, including, but not limited to, individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.

Low-income family means a family whose total annual income does not exceed 100 percent of the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2). ''Low-income family'' also includes members of families whose annual family income exceeds this amount, but who, as determined by the project director, are unable, for good reasons, to pay for family planning services. For example, unemancipated minors who wish to receive services on a confidential basis must be considered on the basis of their own resources.

Nonprofit, as applied to any private agency, institution, or organization, means that no part of the entity's net earnings benefit, or may lawfully benefit, any private shareholder or individual.

Quality healthcare is safe, effective, client-centered, timely, efficient, and equitable.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Service site is a clinic or other location where Title X services (under the Act) are provided to clients. Title X recipients and/or their subrecipients may have service sites.

State includes, in addition to the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the U.S. Virgin Islands, American Samoa, the U.S. Outlaying Islands (Midway, Wage, et al.), the Marshall Islands, the Federated State of Micronesia and the Republic of Palau.

Trauma-informed means a program, organization, or system that is trauma-informed realizes the widespread impact of trauma and understands potential paths for recovery; recognizes the signs and symptoms of trauma in clients, families, staff, and others involved with the system; and responds by fully integrating knowledge about trauma into policies, procedures, and practices, and seeks to actively resist re-traumatization.

§ 59.3 Who is eligible to apply for a family planning services grant?

Any public or nonprofit private entity in a State may apply for a grant under this subpart.

§ 59.4 How does one apply for a family planning services grant?

(a) Application for a grant under this subpart shall be made on an authorized form.

(b) An individual authorized to act for the applicant and to assume on behalf of the applicant the obligations imposed by the terms and conditions of the grant, including the regulations of this subpart, must sign the application.

(c) The application shall contain—

(1) A description, satisfactory to the Secretary, of the project and how it will meet the requirements of this subpart;

(2) A budget and justification of the amount of grant funds requested;

(3) A description of the standards and qualifications which will be required for all personnel and for all facilities to be used by the project; and

(4) Such other pertinent information as the Secretary may require.

§ 59.5 What requirements must be met by a family planning project?

(a) Each project supported under this part must:

(1) Provide a broad range of acceptable and effective medically approved family planning methods (including natural family planning methods) and services (including pregnancy testing and counseling, assistance to achieve pregnancy, basic infertility services, STI services, preconception health services, and adolescent-friendly health services). If an organization offers only a single method of family planning, it may participate as part of a project as long as the entire project offers a broad range of acceptable and effective medically approved family planning methods and services. Title X service sites that are unable to provide clients with access to a broad range of acceptable and effective medically approved family planning methods and services, must be able to provide a referral to the client's method of choice and the referral must not unduly limit the client's access to their method of choice.

(2) Provide services without subjecting individuals to any coercion to accept services or to employ or not to employ any particular methods of family planning. Acceptance of services must be solely on a voluntary basis and may not be made a prerequisite to eligibility for, or receipt of, any other services, assistance from or participation in any other program of the applicant.[1]

(3) Provide services in a manner that is client-centered, culturally and linguistically appropriate, inclusive, and trauma-informed; protects the dignity of the individual; and ensures equitable and quality service delivery consistent with nationally recognized standards of care.

(4) Provide services without regard of religion, race, color, national origin, disability, age, sex, number of pregnancies, or marital status.

(5) Not provide abortion as a method of family planning. A project must:

(i) Offer pregnant clients the opportunity to be provided information and counseling regarding each of the following options:

(A) Prenatal care and delivery;

(B) Infant care, foster care, or adoption; and

(C) Pregnancy termination.

(ii) If requested to provide such information and counseling, provide neutral, factual information and nondirective counseling on each of the options, and referral upon request, except with respect to any option(s) about which the pregnant client indicates they do not wish to receive such information and counseling.

(6) Provide that priority in the provision of services will be given to clients from low-income families.

(7) Provide that no charge will be made for services provided to any clients from a low-income family except to the extent that payment will be made by a third party (including a Government agency) which is authorized to or is under legal obligation to pay this charge.

(8) Provide that charges will be made for services to clients other than those from low-income families in accordance with a schedule of discounts based on ability to pay, except that charges to persons from families whose annual income exceeds 250 percent of the levels set forth in the most recent Poverty Guidelines issued pursuant to 42 U.S.C. 9902(2) will be made in accordance with a schedule of fees designed to recover the reasonable cost of providing services.

(i) Family income should be assessed before determining whether copayments or additional fees are charged.

(ii) With regard to insured clients, clients whose family income is at or below 250% Federal poverty line (FPL) should not pay more (in copayments or additional fees) than what they would otherwise pay when the schedule of discounts is applied.

(9) Take reasonable measures to verify client income, without burdening clients from low-income families. Recipients that have lawful access to other valid means of income verification because of the client's participation in another program may use those data rather than re-verify income or rely solely on clients' self-report. If a client's income cannot be verified after reasonable attempts to do so, charges are to be based on the client's self-reported income.

(10) If a third party (including a Government agency) is authorized or legally obligated to pay for services, all reasonable efforts must be made to obtain the third-party payment without application of any discounts. Where the cost of services is to be reimbursed under title XIX, XX, or XXI of the Social Security Act, a written agreement with the title XIX, XX, or XXI agency is required.

(11)(i) Provide that if an application relates to consolidation of service areas or health resources or would otherwise affect the operations of local or regional entities, the applicant must document that these entities have been given, to the maximum feasible extent, an opportunity to participate in the development of the application. Local and regional entities include existing or potential subrecipients which have previously provided or propose to provide family planning services to the area proposed to be served by the applicant.

(ii) Provide an opportunity for maximum participation by existing or potential subrecipients in the ongoing policy decision making of the project.

(12) Title X projects shall comply with all State and local laws requiring notification or reporting of child abuse,

[1] 42 U.S.C. 300a–8 (Section 205 of Pub. L. 94–63) states: ''Any (1) officer or employee of the United States, (2) officer or employee of any State, political subdivision of a State, or any other entity, which administers or supervises the administration of any program receiving Federal financial assistance, or (3) person who receives, under any program receiving Federal assistance, compensation for services, who coerces or endeavors to coerce any person to undergo an abortion or sterilization procedure by threatening such person with the loss of, or disqualification for the receipt of, any benefit or service under a program receiving Federal financial assistance shall be fined not more than $1,000 or imprisoned for not more than one year, or both.''

child molestation, sexual abuse, rape, incest, intimate partner violence or human trafficking (collectively, ''State notification laws''). Title X projects must provide appropriate documentation or other assurance satisfactory to the Secretary that it:

(i) Has in place and implements a plan to comply with State notification laws.

(ii) Provides timely and adequate annual training of all individuals (whether or not they are employees) serving clients for, or on behalf of, the project regarding State notification laws; policies and procedures of the Title X project and/or for providers with respect to notification and reporting of child abuse, child molestation, sexual abuse, rape, incest, intimate partner violence and human trafficking; appropriate interventions, strategies, and referrals to improve the safety and current situation of the patient; and compliance with State notification laws.

(13) Ensure transparency in the delivery of services by reporting the following information in grant applications and all required reports:

(i) Subrecipients and agencies or individuals providing referral services and the services to be provided;

(ii) Description of the extent of the collaboration with subrecipients, referral agencies, and any individuals providing referral services, in order to demonstrate a seamless continuum of care for clients; and

(iii) Explanation of how the recipient will ensure adequate oversight and accountability for quality and effectiveness of outcomes among subrecipients.

(b) In addition to the requirements of paragraph (a) of this section, each project must meet each of the following requirements unless the Secretary determines that the project has established good cause for its omission. Each project must:

(1) Provide for medical services related to family planning (including consultation by a healthcare provider, examination, prescription, and continuing supervision, laboratory examination, contraceptive supplies) and necessary referral to other medical facilities when medically indicated, and provide for the effective usage of contraceptive devices and practices.

(2) Provide for social services related to family planning, including counseling, referral to and from other social and medical service agencies, and any ancillary services which may be necessary to facilitate clinic attendance.

(3) Provide for opportunities for community education, participation, and engagement to:

(i) Achieve community understanding of the objectives of the program;

(ii) Inform the community of the availability of services; and

(iii) Promote continued participation in the project by diverse persons to whom family planning services may be beneficial to ensure access to equitable, affordable, client-centered, quality family planning services.

(4) Provide for orientation and in-service training for all project personnel.

(5) Provide services without the imposition of any durational residency requirement or requirement that the patient be referred by a physician.

(6) Provide that family planning medical services will be performed under the direction of a physician with special training or experience in family planning.

(7) Provide that all services purchased for project participants will be authorized by the project director or his designee on the project staff.

(8) Provide for coordination and use of referrals and linkages with primary healthcare providers, other providers of healthcare services, local health and welfare departments, hospitals, voluntary agencies, and health services projects supported by other Federal programs, who are in close physical proximity to the Title X site, when feasible, in order to promote access to services and provide a seamless continuum of care.

(9) Provide that if family planning services are provided by contract or other similar arrangements with actual providers of services, services will be provided in accordance with a plan which establishes rates and method of payment for medical care. These payments must be made under agreements with a schedule of rates and payment procedures maintained by the recipient. The recipient must be prepared to substantiate that these rates are reasonable and necessary.

(10) Provide, to the maximum feasible extent, an opportunity for participation in the development, implementation, and evaluation of the project by persons broadly representative of all significant elements of the population to be served, and by others in the community knowledgeable about the community's needs for family planning services.

§ 59.6 What procedures apply to assure the suitability of informational and educational material (print and electronic)?

(a) A grant under this section may be made only upon assurance satisfactory to the Secretary that the project shall provide for the review and approval of informational and educational materials (print and electronic) developed or made available under the project by an Advisory Committee prior to their distribution, to assure that the materials are suitable for the population or community to which they are to be made available and the purposes of Title X of the Act. The project shall not disseminate any such materials which are not approved by the Advisory Committee.

(b) The Advisory Committee referred to in paragraph (a) of this section shall be established as follows:

(1) *Size.* The Committee shall consist of no fewer than five members and up to as many members the recipient determines, except that this provision may be waived by the Secretary for good cause shown.

(2) *Composition.* The Committee shall include individuals broadly representative of the population or community for which the materials are intended (in terms of demographic factors such as race, ethnicity, color, national origin, disability, sex, sexual orientation, gender identity, age, marital status, income, geography, and including but not limited to individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality).

(3) *Function.* In reviewing materials, the Advisory Committee shall:

(i) Consider the educational, cultural, and diverse backgrounds of individuals to whom the materials are addressed;

(ii) Consider the standards of the population or community to be served with respect to such materials;

(ii) Review the content of the material to assure that the information is factually correct, medically accurate, culturally and linguistically appropriate, inclusive, and trauma informed;

(iii) Determine whether the material is suitable for the population or community to which is to be made available; and

(iv) Establish a written record of its determinations.

§ 59.7 What criteria will the Department of Health and Human Services use to decide which family planning services projects to fund and in what amount?

(a) Within the limits of funds available for these purposes, the Secretary may award grants for the

establishment and operation of those projects which will in the Department's judgment best promote the purposes of section 1001 of the Act, taking into account:

(1) The number of clients, and, in particular, the number of low-income clients to be served;

(2) The extent to which family planning services are needed locally;

(3) The ability of the applicant to advance health equity;

(4) The relative need of the applicant;

(5) The capacity of the applicant to make rapid and effective use of the Federal assistance;

(6) The adequacy of the applicant's facilities and staff;

(7) The relative availability of non-Federal resources within the community to be served and the degree to which those resources are committed to the project; and

(8) The degree to which the project plan adequately provides for the requirements set forth in these regulations.

(b) The Secretary shall determine the amount of any award on the basis of his estimate of the sum necessary for the performance of the project. No grant may be made for less than 90 percent of the project's costs, as so estimated, unless the grant is to be made for a project which was supported, under section 1001, for less than 90 percent of its costs in fiscal year 1975. In that case, the grant shall not be for less than the percentage of costs covered by the grant in fiscal year 1975.

(c) No grant may be made for an amount equal to 100 percent for the project's estimated costs.

§ 59.8 How is a grant awarded?

(a) The notice of grant award specifies how long Department of Health and Human Services (HHS) intends to support the project without requiring the project to recompete for funds. This anticipated period will usually be for three to five years.

(b) Generally the grant will initially be for one year and subsequent continuation awards will also be for one year at a time. A recipient must submit a separate application to have the support continued for each subsequent year. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the recipient's progress and management practices, and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the Government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

§ 59.9 For what purpose may grant funds be used?

Any funds granted under this subpart shall be expended solely for the purpose for which the funds were granted in accordance with the approved application and budget, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed in 45 CFR part 75.

§ 59.10 Confidentiality.

All information as to personal facts and circumstances obtained by the project staff about individuals receiving services must be held confidential and must not be disclosed without the individual's documented consent, except as may be necessary to provide services to the patient or as required by law, with appropriate safeguards for confidentiality. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals. Reasonable efforts to collect charges without jeopardizing client confidentiality must be made. Recipient must inform the client of any potential for disclosure of their confidential health information to policyholders where the policyholder is someone other than the client.

§ 59.11 Additional conditions.

The Secretary may, with respect to any grant, impose additional conditions prior to, at the time of, or during any award, when in the Department's judgment these conditions are necessary to assure or protect advancement of the approved program, the interests of public health, or the proper use of grant funds.

§ 59.12 What other HHS regulations apply to grants under this subpart?

Attention is drawn to the following the HHS regulations which apply to grants under this subpart. These include:

TABLE 1 TO § 59.12

37 CFR part 401	Rights to inventions made by nonprofit organizations and small business firms under Government grants, contracts, and cooperative agreements.
42 CFR part 50, subpart D	Public Health Service grant appeals procedure.
45 CFR part 16	Procedures of the Departmental Grant Appeals Board.
45 CFR part 75	Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards.
45 CFR part 80	Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services effectuation of Title VI of the Civil Rights Act of 1964.
45 CFR part 84	Nondiscrimination on the basis of handicap in programs and activities receiving or benefitting from Federal financial assistance.
45 CFR part 87	Equal treatment for faith-based organizations.
45 CFR part 91	Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

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ENVIRONMENTAL PROTECTION AGENCY

48 CFR Parts 1532 and 1552

[EPA–HQ–OMS–2020–0389; FRL–10021–63–OMS]

Environmental Protection Agency Acquisition Regulation (EPAAR); Electronic Invoicing and the Invoice Processing Platform (IPP)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is amending an existing EPAAR clause to further address electronic invoicing at EPA via the Invoice Processing Platform (IPP).

DATES: Comments must be received on or before June 14, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OMS–2020–0389, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Thomas Valentino, Policy, Training and Oversight Division, Acquisition Policy and Training Branch (3802R), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 564–4522; email address: *valentino.thomas@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

1. *Submitting Classified Business Information.* Do not submit CBI to EPA website *https://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI, and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).
- Follow directions—The Agency may ask you to respond to specific questions or organize comments by referencing a *Code of Federal Regulations* (CFR) Part or section number.
- Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
- Describe any assumptions and provide any technical information and/or data that you used.
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- Provide specific examples to illustrate your concerns, and suggest alternatives.
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- Make sure to submit your comments by the comment period deadline identified.

3. Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://;www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room are closed to the public, with limited exceptions, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov/* or email, as there may be a delay in processing mail and faxes. Hand deliveries and couriers may be received by scheduled appointment only. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.* The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

II. Background

The EPA is amending an existing EPAAR clause to further address electronic invoicing at EPA via the Invoice Processing Platform (IPP). Currently EPA has one clause that addresses IPP, which is clause 1552.232–70, *Submission of Invoices.* Clause 1552.232–70 is written for cost-reimbursable and time-and-materials contracts and orders where considerable supporting documentation is required. Such documentation is necessary for those types of contracts and orders but is not necessary for other contract types, like firm-fixed-price (FFP). Therefore, the subject clause is being amended to include other contract and order types like FFP, when it is not suitable to use clause 1552.232–70 in its current form.

III. Proposed Rule

The proposed rule amends EPA Acquisition Regulation (EPAAR) part 1532, *Contract Financing,* by amending § 1532.908, *Contract Clauses.* EPAAR Subpart 1552.2, *Texts of Provisions and Clauses,* is amended by modifying EPAAR § 1552.232–70 and also changing the clause title, from *Submission of Invoices* to *Additional Instructions for Submission of Electronic Invoices via the Invoice Processing Platform (IPP).*

1. EPAAR § 1532.908 amends the prescription for use of § 1552.232–70 by adding a prescription for Alternate 2 use.

2. EPAAR § 1552.232–70, *Submission of Invoices,* is changed to *Additional Instructions for Submission of Electronic Invoices via the Invoice Processing Platform (IPP),* and adds an Alternate 2.

IV. Statutory and Executive Orders Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a ''significant regulatory action'' under the terms of Executive Order (E.O.) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the E.O.

B. Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* Burden is defined at 5 CFR 1320.3(b).

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute; unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions. For purposes of assessing the impact of this proposed rule on small entities, ''small entity'' is defined as: (1) A small business that meets the definition of a small business found in the Small Business Act and codified at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; or (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field. After considering the economic impacts of this rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. In determining whether a rule has a significant economic impact on a substantial number of small entities, the impact of concern is any significant adverse economic impact on small entities, because the primary purpose of the regulatory flexibility analyses is to identify and address regulatory alternatives ''which minimize any significant economic impact of the proposed rule on small entities'' 5 U.S.C. 503 and 604. Thus, an agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, or otherwise has a positive economic effect on all of the small entities subject to the rule. This action establishes a new EPAAR clause that will not have a significant economic impact on a substantial number of small entities. We continue to be interested in the potential impacts of the rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA, Pub. L. 104–4), establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, Local, and Tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of the Title II of the UMRA) for State, Local, and Tribal governments or the private sector. The rule imposes no enforceable duty on any State, Local or Tribal governments or the private sector. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

E. Executive Order 13132: Federalism

Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and Local officials in the development of regulatory policies that have federalism implications. ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This rule does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government as specified in Executive Order 13132.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' This rule does not have tribal implications as specified in Executive Order 13175.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045, entitled ''Protection of Children from Environmental Health and Safety Risks'' (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be economically significant as defined under E.O. 12886, and (2) concerns an environmental health or safety risk that may have a proportionate effect on children. This rule is not subject to E.O. 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because it does not involve decisions on environment health or safety risks.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use'' (66 FR 28335 (May 22, 2001), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act of 1995 (NTTAA)

Section 12(d) (15 U.S.C. 272 note) of the National Technology Transfer and Advancement Act of 1995, Public Law 104–113, directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.,* materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards. This action does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to

make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment in the general public.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a major rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. Section 804(2) defines a ''major rule'' as any rule that the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget finds has resulted in or is likely to result in (1) an annual effect on the economy of $100,000,000 or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. EPA is not required to submit a rule report regarding this action under section 801 as this is not a major rule by definition.

List of Subjects in 48 CFR Parts 1532 and 1552

Environmental protection, Accounting, Government procurement, Reporting and recordkeeping requirements.

Kimberly Patrick,

Director, Office of Acquisition Solutions.

For the reasons set forth in the preamble, EPA proposes to amend EPAAR parts 1532 and 1552 as follows:

PART 1532—CONTRACT FINANCING

■ 1. The authority citations for part 1532 continue to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b.

■ 2. Revise § 1532.908 to read as follows:

1532.908 Contract clause.

(a)(i) The Contracting Officer shall insert clause 1552.232–70 in cost-reimbursable procurements.

(ii) The Contracting Officer shall insert clause 1552.232–70 Alternate 1 in fixed-rate and non-commercial time & materials (T&M) procurements.

(iii) The Contracting Officer shall insert clause 1552.232–70 Alternate 2 in all other procurements where electronic invoicing via the Invoice Processing Platform (IPP) is required EXCEPT for simplified acquisitions (for instance, use Alternate 2 for contract/order types such as firm-fixed-price, commercial items, architect-engineering and construction).

(b) In addition to clause 1552.232–70, Contracting Officers must also select the appropriate Federal Acquisition Regulation (FAR) clause to include in the subject procurement in accordance with FAR 32.908, *as applicable.*

PART 1552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citations for part 1552 continue to read as follows:

Authority: 5 U.S.C. 301 and 41 U.S.C. 418b and 1707.

■ 4. Revise § 1552.232–70, to read as follows:

§ 1552.232–70 Additional Instructions for Submission of Electronic Invoices via the Invoice Processing Platform (IPP).

As prescribed in 1532.908, insert the following clause:

Additional Instructions for Submission of Electronic Invoices Via the Invoice Processing Platform (IPP) (date)

(a) *Electronic invoicing and the Invoice Processing Platform (IPP)*—(1) *Definitions.* As used in this clause—

Contract financing payment and *invoice payment* are defined in Federal Acquisition Regulation (FAR) 32.001.

Electronic form means an automated system that transmits information electronically from the initiating system to all affected systems. Facsimile, email, and scanned documents are not acceptable electronic forms for submission of payment requests. However, scanned documents are acceptable when they are part of a submission of a payment request made using Invoice Processing Platform or another electronic form authorized by the Contracting Officer.

Payment request means any request for contract financing payment or invoice payment submitted by the Contractor under this contract.

(2)(i) Except as provided in paragraph (c) of this clause, the Contractor shall submit invoices using the electronic invoicing program Invoice Processing Platform (IPP), which is a secure web-based service provided by the U.S. Treasury that more efficiently manages government invoicing.

(ii) Under this contract, the following documents are required to be submitted as an attachment to the IPP invoice: (This is a fill-in for acceptable types of required documentation, such as an SF 1034 and 1035, or an invoice/self-designed form on company letterhead that contains the required information.)

(iii) The Contractor's Government Business Point of Contact (as listed in System for Award Management (SAM)) will receive enrollment instructions via email from the IPP. The Contractor must register within 3 to 5 days of receipt of such email from IPP.

(iv) Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email at *IPPCustomerSupport@fiscal.treasury.gov* or by telephone at (866) 973–3131.

(3) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment, the Contractor shall submit a waiver request in writing to the Contracting Officer. The Contractor may submit an invoice using other than IPP only when—

(i) The Contracting Officer administering the contract for payment has determined, in writing, that electronic submission would be unduly burdensome to the Contractor; and in such cases, the Contracting Officer shall modify the contract to include a copy of the Determination; or

(ii) When the Governmentwide commercial purchase card is used as the method of payment.

(4) The Contractor shall submit any non-electronic payment requests using the method or methods specified in Section G of the contract.

(5) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payment requests.

(6) Invoices submitted through IPP will be either rejected, or accepted and paid, in their entirety, and will not be paid on a partial basis.

(b) *Invoice preparation.* The Contractor shall prepare its invoice or request for contract financing payment in accordance with FAR 32.905 on the prescribed Government forms, or the Contractor may submit self-designed forms which contain the required information. Standard Form 1034, *Public Voucher for Purchases and Services other than Personal,* is prescribed for used by contractors to show the amount claimed for reimbursement. Standard Form 1035, *Public Voucher for Purchases and Services other than Personal—Continuation Sheet,* is prescribed for use to furnish the necessary supporting detail or additional information required by the Contracting Officer.

(c) *Invoice content.* (1) The Contractor shall prepare a contract level invoice or request for contract financing payment in accordance with the invoice preparation instructions. If contract work is authorized by an individual task order or delivery order (TO/DO), the invoice or request for contract financing

payment shall also include a summary of the current and cumulative amounts claimed by cost element for each TO/DO and for the contract total, as well as any supporting data for each TO/DO as identified in the instructions.

(2) The invoice or request for contract financing payment shall include current and cumulative charges by major cost element such as direct labor, overhead, travel, equipment, and other direct costs. For current costs, each major cost element shall include the appropriate supporting schedule identified in the invoice preparation instructions. Cumulative charges represent the net sum of current charges by cost element for the contract period.

(d) *Subcontractor charges.* (1) The charges for subcontracts shall be further detailed in a supporting schedule showing the major cost elements for each subcontract.

(2) On a case-by-case basis, when needed to verify the reasonableness of subcontractor costs, the Contracting Officer may require that the contractor obtain from the subcontractor cost information in the detail set forth in paragraph (c)(2) of this section. This information should be obtained through a means which maintains subcontractor confidentiality (for example, via sealed envelopes), if the subcontractor expresses Confidential Business Information (CBI) concerns.

(e) *Period of performance indication.* Invoices or requests for contract financing payment must clearly indicate the period of performance for which payment is requested. Separate invoices or requests for contract financing payment are required for charges applicable to the base contract and each option period.

(f) *Invoice submittal.* (1) Notwithstanding the provisions of the clause of this contract at FAR 52.216–7, *Allowable Cost and Payment,* invoices or requests for contract financing payment shall be submitted once per month unless there has been a demonstrated need and Contracting Officer approval for more frequent billings. When submitted on a monthly basis, the period covered by invoices or requests for contractor financing payments shall be the same as the period for monthly progress reports required under this contract.

(2) If the Contracting Officer allows submissions more frequently than monthly, one submittal each month shall have the same ending period of performance as the monthly progress report.

(3) Where cumulative amounts on the monthly progress report differ from the aggregate amounts claimed in the invoice(s) or request(s) for contract financing payments covering the same period, the contractor shall provide a reconciliation of the difference as part of the payment request.

(g) *Invoice Preparation Instructions—SF 1034.* The information which a contractor is required to submit in its Standard Form 1034 is set forth as follows:

(1) U.S. Department, Bureau, or establishment and location—Insert the names and address of the servicing finance office, unless the contract specifically provides otherwise.

(2) Date Voucher Prepared—Insert date on which the public voucher is prepared and submitted.

(3) Contract/Delivery Order Number and Date—Insert the number and date of the contract and task order or delivery order, if applicable, under which reimbursement is claimed.

(4) Requisition Number and Date—Leave blank.

(5) Voucher Number—Insert the appropriate serial number of the voucher. A separate series of consecutive numbers, beginning with Number 1, shall be used by the contractor for each new contract. For an adjustment invoice, write ''[*invoice number*] #Adj'' at the voucher number. For a final invoice, put invoice number F. For a completion invoice, put invoice number #C.

(6) Schedule Number; Paid By; Date Invoice Received—Leave blank.

(7) Discount Terms—Enter terms of discount, if applicable.

(8) Payee's Account Number—This space may be used by the contractor to record the account or job number(s) assigned to the contract or may be left blank.

(9) Payee's Name and Address—Show the name of the contractor exactly as it appears in the contract and its correct address, except when an assignment has been made by the contractor, or the right to receive payment has been restricted, as in the case of an advance account. When the right to receive payment is restricted, the type of information to be shown in this space shall be furnished by the Contracting Officer.

(10) Shipped From; To; Weight Government B/L Number—Insert for supply contracts.

(11) Date of Delivery or Service—Show the month, day and year, beginning and ending dates of incurrence of costs claimed for reimbursement. Adjustments to costs for prior periods should identify the period applicable to their incurrence, *e.g.,* revised provisional or final indirect cost rates, award fee, etc.

(12) Articles or Services—Insert the following: ''For detail, see Standard Form 1035 total amount claimed transferred from Page __of Standard Form 1035.'' Insert ''COST REIMBURSABLE—PROVISIONAL PAYMENT'' or ''INDEFINITE QUANTITY/INDEFINITE DELIVERY—PROVISIONAL PAYMENT'' on the Interim public vouchers. Insert ''COST REIMBURSABLE—COMPLETION VOUCHER'' or ''INDEFINITE QUANTITY/INDEFINITE DELIVERY—COMPLETION VOUCHER'' on the Completion public voucher. Insert ''COST REIMBURSABLE—FINAL VOUCHER'' or ''INDEFINITE QUANTITY/INDEFINITE DELIVERY—FINAL VOUCHER'' on the final public voucher. Insert the following certification, signed by an authorized official, on the face of the Standard Form 1034:

''I certify that all payments requested are for appropriate purposes and in accordance with the agreements set forth in the contract.''

(Name of Official)

(Title)

(13) Quantity; Unit Price—Insert for supply contracts.

(14) Amount—Insert the amount claimed for the period indicated in paragraph (g)(11) of this clause.

(h) *Invoice Preparation Instructions—SF 1035.* The information which a contractor is required to submit in its Standard Form 1035 is set forth as follows:

(1) U.S. Department, Bureau, or Establishment—Insert the name and address of the servicing finance office.

(2) Voucher Number—Insert the voucher number as shown on the Standard Form 1034.

(3) Schedule Number—Leave blank.

(4) Sheet Number—Insert the sheet number if more than one sheet is used in numerical sequence. Use as many sheets as necessary to show the information required.

(5) Number and Date of Order—Insert payee's name and address as in the Standard Form 1034.

(6) Articles or Services—Insert the contract number as in the Standard Form 1034.

(7) Amount—Insert the latest estimated cost, fee (fixed, base, or award, as applicable), total contract value, and amount and type of fee payable (as applicable).

(8) A summary of claimed current and cumulative costs and fee by major cost element—Include the rate(s) at which indirect costs are claimed and indicate the base of each by identifying the line of costs to which each is applied. The rates invoiced should be as specified in the contract or by a rate agreement negotiated by EPA's Cost and Rate Negotiation Team.

(9) Fee—The fee shall be determined in accordance with instructions appearing in the contract.

Note to paragraph (h)—Amounts claimed on vouchers must be based on records maintained by the contractor to show by major cost element the amounts claimed for reimbursement for each applicable contract. The records must be maintained based on the contractor's fiscal year and should include reconciliations of any differences between the costs incurred and amounts claimed for reimbursement. A memorandum record reconciling the total indirect cost(s) claimed should also be maintained.

(i) *Supporting Schedules for Cost Reimbursement Contracts.* The following backup information is required as an attachment to the invoice as shown by category of cost:

(1) Direct Labor—Identify the number of hours (by contractor labor category and total) and the total loaded direct labor hours billed for the period in the invoice.

(2) Indirect Cost Rates—Identify by cost center, the indirect cost rate, the period, and the cost base to which it is applied.

(3) Subcontracts—Identify the major cost elements for each subcontract.

(4) Other Direct Costs—When the cost for an individual cost (*e.g.,* photocopying, material and supplies, telephone usage) exceeds $1,000 per the invoice period, provide a detailed explanation for that cost category.

(5) Contractor Acquired Equipment (if authorized by the contract)—Identify by item the quantities, unit prices, and total dollars billed.

(6) Contractor Acquired Software (if authorized by the contract)—Identify by item the quantities, unit prices, and total dollars billed.

(7) Travel—When travel costs exceed $2,000 per invoice period, identify by trip, the number of travelers, the duration of travel, the point of origin, destination, purpose of trip, transportation by unit price, per diem rates on daily basis and total dollars billed. Detailed reporting is not required for local travel. The manner of breakdown, *e.g.,* task order/delivery order basis with/without separate program management, contract period will be specified in the contract instructions.

Note to paragraph (i) —Any costs requiring advance consent by the Contracting Officer will be considered improper and will be disallowed, if claimed prior to receipt of Contracting Officer consent. Include the total cost claimed for the current and cumulative-to-date periods. After the total amount claimed, provide summary dollar amounts disallowed on the contract as of the date of the invoice. Also include an explanation of the changes in cumulative costs disallowed by addressing each adjustment in terms of: Voucher number, date, dollar amount, source, and reason for the adjustment. Disallowed costs should be identified in unallowable accounts in the contractor's accounting system.

(j) *Supporting Schedules for Time and Materials Contracts.* The following backup information is required as an attachment to the invoice as shown by category of cost:

(1) Direct Labor—Identify the number of hours (by contractor labor category and total) and the total direct labor hours billed for the period of the invoice.

(2) Subcontracts—Identify the major cost elements for each subcontract.

(3) Other Direct Costs—When the cost for an individual cost (*e.g.,* photocopying, material and supplies, telephone usage) exceeds $1,000 per the invoice period, provide a detailed explanation for that cost category.

(4) Indirect Cost Rates—Identify by cost center, the indirect cost rate, the period, and the cost base to which it is applied.

(5) Contractor Acquired Equipment—Identify by item the quantities, unit prices, and total dollars billed.

(6) Contractor Acquired Software—Identify by item the quantities, unit prices, and total dollars billed.

(7) Travel—When travel costs exceed $2,000 per invoice period, identify by trip, the number of travelers, the duration of travel, the point of origin, destination, purpose of trip, transportation by unit price, per diem rates on daily basis and total dollars billed. Detailed reporting is not required for local travel. The manner of breakdown, *e.g.,* task order/delivery order basis with/without separate program management, contract period will be specified in the contract instructions.

Note to paragraph (j) —Any costs requiring advance consent by the Contracting Officer will be considered improper and will be disallowed, if claimed prior to receipt of Contracting Officer consent. Include the total cost claimed for the current and cumulative-to-date periods. After the total amount claimed, provide summary dollar amounts disallowed on/the contract as of the date of the invoice. Also include an explanation of the changes in cumulative costs disallowed by addressing each adjustment in terms of: Voucher number, date, dollar amount, source, and reason for the adjustment. Disallowed costs should be identified in unallowable accounts in the contractor's accounting system.

(k) *Adjustment vouchers.* Adjustment vouchers should be submitted if finalized indirect rates were received but the rates are not for the entire period of performance. For example, the base period of performance is for a calendar year but your indirect rates are by fiscal year. Hence, only part of the base period can be adjusted for the applicable final indirect rates. These invoices should be annotated with ''adj'' after the invoice number.

(l) *Final vouchers.* Final Vouchers shall be submitted if finalized rates have been received for the entire period of performance. For example, the base period of performance is for a calendar year but your indirect rates are by fiscal year. You have received finalized rates for the entire base period that encompass both fiscal years that cover the base period. In accordance with FAR 52.216–7, these invoices shall be submitted within 60 days after settlement of final indirect cost rates. They should be annotated with the word ''Final'' or ''F'' after the invoice number. Due to system limitations, the invoice number cannot be more than 11 characters to include spaces.

(m) *Completion vouchers.* In accordance with FAR 52.216–7(d)(5), a completion voucher shall be submitted within 120 days (or longer if approved in writing by the Contracting Officer) after settlement of the final annual indirect cost rates for all years of a physically complete contract. The voucher shall reflect the settled amounts and rates. It shall include settled subcontract amounts and rates. The prime contractor is responsible for settling subcontractor amounts and rates included in the completion invoice. Since EPA's invoices must be on a period of performance basis, the contractor shall have a completion invoice for each year of the period of performance. This voucher must be submitted to the Contracting Officer for review and approval before final payment can be made on the contract. The Contracting Officer may request an audit of the completion vouchers before final payment is made. In addition, once approved, the Contracting Officer will request the appropriate closeout paperwork for the contract. For contracts separately invoiced by delivery or task order, provide a schedule showing final total costs claimed by delivery or task order and in total for the contract. In addition to the completion voucher, the contractor must submit the *Contractor's Release; Assignee's Release,* if applicable; the *Contractor's Assignment of Refunds, Rebates, Credits and other Amounts;* the *Assignee's Assignment of Refunds, Rebates, Credits and other Amounts,* if applicable; and the *Contractor's Affidavit of Waiver of Lien,* when required by the contract.

Alternate 1 (For use in fixed-rate and non-commercial time & materials (T&M) procurements) (*date*). If the procurement is fixed-rate or non-commercial T&M, substitute the basic (c)(2) paragraph with the following:

(c)(2) The invoice or request for contract financing payment that employs a fixed rate feature shall include current and cumulative charges by contract labor category and by other major cost elements such as travel, equipment, and other direct costs. For current costs, each cost element shall include the appropriate supporting schedules identified in the invoice preparation instructions.

Alternate 2 (For use in all other procurements where electronic invoicing via the Invoice Processing Platform (IPP) is required EXCEPT for simplified acquisitions)(*date*). Use Alternate 2 for contract/order types such as firm-fixed-price, commercial items, architect-engineering and construction for IPP purposes.

(a) *Definitions.* As used below—

Contract financing payment and *invoice payment* are defined in Federal Acquisition Regulation (FAR) 32.001.

Electronic form means an automated system that transmits information electronically from the initiating system to all affected systems. Facsimile, email, and scanned documents are not acceptable electronic forms for submission of payment requests. However, scanned documents are acceptable when they are part of a submission of a payment request made using Invoice Processing Platform or another electronic form authorized by the Contracting Officer.

Payment request means any request for contract financing payment or invoice payment submitted by the Contractor under this contract.

(b)(1) The Contractor shall submit invoices using the electronic form invoicing program Invoice Processing Platform (IPP), which is a secure web-based service provided by the U.S. Treasury that more efficiently manages government invoicing.

(2) The Contractor's Government Business Point of Contact (as listed in System for Award Management (SAM)) will receive registration/enrollment instructions via email from the IPP. Registration is free and the Contractor must register within 3 to 5 days of receipt of such email from IPP.

(3) Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email at *IPPCustomerSupport@fiscal.treasury.gov* or by telephone at (866) 973–3131.

(c) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment, the Contractor shall submit a waiver request in writing to the Contracting Officer. The Contractor may submit an invoice using other than IPP only when—

(1) The Contracting Officer administering the contract for payment has determined, in writing, that electronic form submission would be unduly burdensome to the Contractor; and in such cases, the Contracting Officer shall modify the contract to include a copy of the Determination; or

(2) When the Governmentwide commercial purchase card is used as the method of payment.

(d) The Contractor shall submit any non-electronic form payment requests using the method or methods specified in the contract.

(e) Invoices submitted through IPP will be either rejected, or accepted and paid, in their entirety, and will not be paid on a partial basis.

(f) In addition to the requirements of this clause, the Contractor shall meet the requirements of the appropriate payment clauses in this contract when submitting payment requests.

(g) If there are any additional invoice instructions then please insert them below:

(End of clause)

[FR Doc. 2021–07580 Filed 4–14–21; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket Nos. FWS–R4–ES–2017–0061 and FWS–R4–ES–2020–0137; FF09E2100 FXES11110900000 212]

RIN 1018–BC14; 1018–BD50

Endangered and Threatened Wildlife and Plants; Threatened Species Status, Section 4(d) Rule, and Designation of Critical Habitat for Panama City Crayfish

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of comment period and announcement of public hearing.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), reopen the public comment period on the proposed rule to list the Panama City crayfish (*Procambarus econfinae*) as a threatened species under the Endangered Species Act of 1973, as amended (Act); propose a rule issued under section 4(d) of the Act (''4(d) rule'') for the species; and propose to designate critical habitat for the Panama City crayfish under the Act. In total, approximately 7,177 acres (2,904 hectares) in Bay County, Florida, fall within the boundaries of the proposed critical habitat designation, all of which are currently occupied by the species. We also announce the availability of a draft economic analysis (DEA) for the proposed designation of critical habitat for the Panama City crayfish. We will accept comments on the proposed listing, 4(d) rule, and critical habitat designation, as well as the draft economic analysis, during the open comment period. Finally, we announce a public informational meeting and public hearing on the proposed listing rule and this proposed rule.

DATES:

Written comments: The comment period on the proposed rule that published January 3, 2018 (83 FR 330), is reopened. We will accept comments on that proposed rule, as well as the new proposals described in this document, that are received or postmarked on or before June 14, 2021. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

Public informational meeting and public hearing: We will hold a public informational meeting on May 4, 2021, from 6 p.m. to 7:30 p.m., Central Time, followed by a public hearing from 7:30 p.m. to 8:30 p.m., Central Time.

ADDRESSES: You may submit comments on the proposed rules or draft economic analysis by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter Docket No. FWS–R4–ES–2017–0061 for the proposed listing, or FWS–R4–ES–2020–0137 for the proposed 4(d) rule and critical habitat designation (including the associated draft economic analysis), which are the docket numbers for the rulemakings. Then, click on the Search button. On the resulting page, in the Search panel on the left side of the screen, under the Document Type heading, check the Proposed Rule box to locate the correct document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail to: Public Comments Processing, Attn: [Docket No. FWS–R4–ES–2017–0061 for the proposed listing, or FWS–R4–ES–2020–0137 for the proposed 4(d) rule and critical habitat designation (including the associated draft economic analysis)], U.S. Fish and Wildlife Service, MS: PRB/3W, 5275 Leesburg Pike, Falls Church, VA 22041–3803.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested, below, for more information).

Public informational meeting and public hearing: The public informational meeting and the public hearing will be held virtually using the Zoom platform. See *Public Hearing,* below, for more information.

Availability of supporting materials: For the proposed critical habitat designation, the shapefiles from which the maps are generated are included in the administrative record and are available at *http://www.regulations.gov* under Docket No. FWS–R4–ES–2020–0137. Any additional tools or supporting information that we may develop for the critical habitat designation may also be included in the preamble and/or at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jay Herrington, Field Supervisor, U.S. Fish and Wildlife Service, Florida Ecological Services Field Office, 1601 Balboa Avenue, Panama City, FL 32405; telephone 904–731–3191; facsimile 904–731–3045. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under section 4(d) of the Act, whenever any species is listed as a threatened species, we are required to issue any regulations deemed necessary and advisable to provide for the conservation of such species. Also, any species that is determined to be endangered or threatened under the Act requires critical habitat to be designated, to the maximum extent prudent and determinable. The Panama City crayfish is proposed as a threatened species under the Act, and this document proposes regulations we deem necessary and advisable under section 4(d) of the Act, and also proposes to designate critical habitat. Designations and revisions of critical habitat can only be completed by issuing a rule. In light of the time that has passed since the publication of the proposed listing rule and the receipt of new scientific information, we are also reopening the comment period for the proposed listing rule.

What this document does. We are concurrently reopening the comment period for the proposed listing rule, proposing a 4(d) rule, and proposing to designate critical habitat for the Panama City crayfish. A draft economic analysis on impacts expected from the critical habitat proposal is also available.

The basis for our action. Under the Act, we may determine that a species is an endangered or threatened species because of any of five factors: (A) The present or threatened destruction, modification, or curtailment of its

habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Our proposed rule identified habitat loss and fragmentation from development (Factor A) as a primary threat to the Panama City crayfish, making the species warranted for protection as a threatened species under the Act.

The Act provides a specific list of prohibitions for endangered species under section 9, but the Act does not automatically extend these same prohibitions to threatened species. Under section 4(d), the Act instructs the Secretary of the Interior (Secretary) to issue any protective regulations deemed necessary and advisable for the conservation of threatened species. It also indicates the Secretary may extend some or all of the prohibitions in section 9 to threatened species. We are proposing a 4(d) rule that specifically tailors measures that provide for the conservation of the Panama City crayfish.

Section 4(a)(3) of the Act requires the Secretary to designate critical habitat concurrent with listing to the maximum extent prudent and determinable. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

We prepared an economic analysis of the proposed designation of critical habitat. In order to consider economic impacts, we prepared an analysis of the economic impacts of the proposed critical habitat designation. We hereby announce the availability of the draft economic analysis and seek public review and comment.

Peer review. In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994 (59 FR 34270), and our August 22, 2016, memorandum updating and clarifying the role of peer review of listing actions under the Act, we sought the expert opinions of nine appropriate specialists regarding version 1.1 of the species status assessment (SSA) report, and four appropriate specialists regarding version 2.0 of the SSA report. We received responses from four specialists for each version (total of eight peer reviews), which informed this proposed rule. The purpose of peer review is to ensure that our listing determinations, critical habitat designations, and 4(d) rules are based on scientifically sound data, assumptions, and analyses. The peer reviewers have expertise in the species' biology, habitat, and response to threats.

Information Requested

We intend that any final action resulting from this proposed rule will be based on the best scientific and commercial data available and be as accurate and as effective as possible. Therefore, we request comments or information from other government agencies, Native American Tribes, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The historical and current status and distribution of the Panama City crayfish, its biology and ecology, specific threats (or lack thereof) and regulations that may be addressing those threats and ongoing conservation measures for the species and its habitat.

(2) Information relevant to the factors that are the basis for making a listing determination for a species under section 4(a) of the Act, which are:

(a) The present or threatened destruction, modification, or curtailment of the species' habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence and threats to the species or its habitat.

(3) The reasons why we should or should not designate habitat as ''critical habitat'' under section 4 of the Act (16 U.S.C. 1531 *et seq.*), including information to inform the following factors that the regulations identify as reasons why designation of critical habitat may be not prudent:

(a) The species is threatened by taking or other human activity and identification of critical habitat can be expected to increase the degree of such threat to the species;

(b) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(c) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States; or

(d) No areas meet the definition of critical habitat.

(4) Specific information on:

(a) The amount and distribution of Panama City crayfish habitat;

(b) What areas, that are occupied at the time of listing and that contain the physical or biological features essential to the conservation of the species, should be included in the designation and why;

(c) Special management considerations or protection that may be needed in critical habitat areas we are proposing, including managing for the potential effects of climate change;

(d) What areas not occupied at the time of listing are essential for the conservation of the species and why;

(e) Information about conservation efforts that may affect proposed critical habitat areas; and

(f) Information about the proposed 100-meter (328-foot) buffer within secondary soils, and whether we should consider increasing or decreasing that buffer.

(5) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat.

(6) Information on the projected and reasonably likely impacts of climate change on the Panama City crayfish and proposed critical habitat.

(7) Any probable economic, national security, or other relevant impacts of designating any area that may be included in the final designation, and the benefits of including or excluding specific areas.

(8) Information on the extent to which the description of probable economic impacts in the draft economic analysis is a reasonable estimate of the likely economic impacts and the description of the environmental impacts in the draft environmental assessment is complete and accurate, especially in light of impacts from Hurricane Michael in October 2018.

(9) Whether any specific areas we are proposing for critical habitat designation should be considered for exclusion under section 4(b)(2) of the

Act, and whether the benefits of potentially excluding any specific area outweigh the benefits of including that area under section 4(b)(2) of the Act.

(10) Whether we could improve or modify our approach to designating critical habitat in any way to provide for greater public participation and understanding, or to better accommodate public concerns and comments.

(11) Information on regulations that are necessary and advisable to provide for the conservation of the Panama City crayfish and that the Service can consider in developing a 4(d) rule for the species. In particular, information concerning the extent to which we should include any of the section 9 prohibitions in the 4(d) rule or whether any other forms of take should be excepted from the prohibitions in the 4(d) rule.

Please include sufficient information with your submission (such as scientific journal articles or other publications) to allow us to verify any scientific or commercial information you include.

Please note that submissions merely stating support for, or opposition to, the action under consideration without providing supporting information, although noted, will not be considered in making a determination, as section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or a threatened species must be made ''solely on the basis of the best scientific and commercial data available.'' Comments previously submitted need not be resubmitted, as they will be fully considered in preparation of the final rule.

You may submit your comments and materials concerning this proposed rule by one of the methods listed in **ADDRESSES**. We request that you send comments only by the methods described in the **ADDRESSES**.

If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the website. If your submission is made via a hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we used in preparing this proposed rule, will be available for public inspection on *http://www.regulations.gov.*

Because we will consider all comments and information we receive during the comment period, our final determinations may differ from this proposal. Based on the new information we receive (and any comments on that new information), we may conclude that the species is endangered instead of threatened, or we may conclude that the species does not warrant listing as either an endangered species or a threatened species. In addition, we may change the parameters of the prohibitions or the exceptions to those prohibitions if we conclude it is appropriate in light of comments and new information received. For example, we may expand the incidental-take prohibitions to include prohibiting additional activities if we conclude that those additional activities are not compatible with conservation of the species. Conversely, we may establish additional exceptions to the incidental-take prohibitions in the final rule if we conclude that the activities would facilitate or are compatible with the conservation and recovery of the species. For critical habitat, our final designation may not include all areas proposed, may include some additional areas, and may exclude some areas if we find the benefits of exclusion outweigh the benefits of inclusion.

Public Hearing

We are holding a public informational meeting followed by a public hearing on the date and at the time listed in **DATES**. We are holding the public informational meeting and public hearing via the Zoom online video platform and via teleconference so that participants can attend remotely. For security purposes, registration is required. To listen and view the meeting and hearing via Zoom, listen to the meeting and hearing by telephone, or provide oral public comments at the public hearing by Zoom or telephone, you must register. For information on how to register, or if you encounter problems joining Zoom the day of the meeting, visit *http://www.fws.gov/panamacity.* Registrants will receive the Zoom link and the telephone number for the public informational meeting and public hearing. If applicable, interested members of the public not familiar with the Zoom platform should view the Zoom video tutorials (*https://support.zoom.us/hc/en-us/articles/206618765-Zoom-video-tutorials*) prior to the public informational meeting and public hearing.

We are holding the public informational meeting to present information about the January 3, 2018, proposed rule to list the Panama City crayfish as a threatened species (83 FR 330) and to provide interested parties an opportunity to ask questions about the proposed 4(d) rule and proposed designation of critical habitat. The public hearing will provide interested parties an opportunity to present verbal testimony (formal, oral comments) regarding the January 3, 2018, proposed rule to list the Panama City crayfish as a threatened species (83 FR 330), the proposed 4(d) rule, and the proposed designation of critical habitat. While the public informational meeting will be an opportunity for dialogue with the Service, the public hearing is not: It is a forum for accepting formal verbal testimony. In the event there is a large attendance, the time allotted for oral statements may be limited. Therefore, anyone wishing to make an oral statement at the public hearing for the record is encouraged to provide a prepared written copy of their statement to us through the Federal eRulemaking Portal, or U.S. mail (see **ADDRESSES**, above). There are no limits on the length of written comments submitted to us. Anyone wishing to make an oral statement at the public hearing must register before the hearing (*http://www.fws.gov/panamacity*). The use of a virtual public hearing is consistent with our regulations at 50 CFR 424.16(c)(3).

Reasonable Accommodation

The Service is committed to providing access to the public informational meeting and public hearing for all participants. Closed captioning will be available during the public informational meeting and public hearing. Further, a full audio and video recording and transcript of the public hearing will be posted online at *http://www.fws.gov/panamacity* after the hearing. Participants will also have access to live audio during the public informational meeting and public hearing via their telephone or computer speakers. Persons with disabilities requiring reasonable accommodations to participate in the meeting and/or hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** at least 5 business days prior to the date of the meeting and hearing to help ensure availability. An accessible version of the Service's public informational meeting presentation will also be posted online at *http://www.fws.gov/panamacity* prior to the meeting and hearing (see **DATES**, above). See *http://www.fws.gov/panamacity* for more information about reasonable accommodation.

Previous Federal Actions

All previous Federal actions are described in the proposal to list the Panama City crayfish as a threatened species under the Act published in the **Federal Register** on January 3, 2018 (83 FR 330).

Supporting Documents

A species status assessment (SSA) team prepared an SSA report for the Panama City crayfish. The SSA team was composed of Service biologists, in consultation with other species experts. The SSA report represents a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species. The Service sent version 1.1 of the SSA report to nine independent peer reviewers and received four responses. The Service also sent the SSA report to two academic partners for review, and we received review from both partners. The Service sent version 2.0 of the SSA report to four peer reviewers and received four responses.

Background

It is our intent to discuss in this document only those topics directly relevant to the new scientific information procured and analyzed since the proposed listing rule's publication, in addition to discussing the proposed section 4(d) rule and designation of critical habitat for the Panama City crayfish. For more information on the Panama City crayfish generally, refer to the proposed listing rule published in the **Federal Register** on January 3, 2018 (83 FR 330). A thorough review of the taxonomy, life history, and ecology of the Panama City crayfish (*Procambarus econfinae*) is presented in the revised SSA report, version 2.0 (Service 2019).

Species Description

The Panama City crayfish is a small, semi-terrestrial crayfish that grows to about 2 inches (in) (50.8 millimeters (mm)) in length (minus claws), and is found in south-central Bay County, Florida. The species' color pattern consists of a medium dark-brown background color, lighter brown mid-dorsal stripe, and darker brown dorsolateral stripes (FWC 2016, p. 1). The Panama City crayfish was first described by Hobbs in 1942 from Bay County, Panama City, Florida. Currently, the Panama City crayfish is classified in the family Cambaridae and is considered a valid taxon by the scientific community (Taylor et al. 1996, 2007; Integrated Taxonomic Information System 2017).

The life history of the Panama City crayfish specifically is not well known. Cambarid crayfish may live about 2.5 to 3 years (Hobbs 2001, p. 977), with a generation period of 2 years. For this family of crayfish, the majority breed more than once, with mating among mature yearlings frequent; however, many individuals do not become sexually active until late summer or fall. Females may produce between 30 and 160 eggs and have been found with eggs and/or young from March through September. Juveniles are most frequently found in the summer and have been observed through December, so young appear to be produced from at least March through December. Juveniles can be carried overland by moving water during rainy periods, which aids in dispersal (Keppner and Keppner 2002, p. 11).

Eight crayfish species occur within the range of the Panama City crayfish, although only the hatchet crayfish, *Procambarus kilbyi,* and the jackknife crayfish, *Procambarus hubbelli,* are found in the same habitat as the Panama City crayfish and may co-occur with it (FWC 2017). The Panama City crayfish is not known to hybridize with other species of crayfish.

Historically, the species inhabited natural and often temporary bodies of shallow fresh water within open pine flatwoods and wet prairie-marsh communities. However, most of these communities have been cleared for residential or commercial development or replaced with slash pine plantations. The Panama City crayfish currently inhabits the waters of grassy, gently sloped ditches and swales, slash pine plantations, utility rights-of-way, and a few remnant parcels protected under wetland and private easements (FWC 2016, p. 2).

The highest densities of Panama City crayfish have been recorded in areas with little to no shrub or tree cover (FWC 2016, p. 2). Suitable habitat is normally dominated by herbaceous vegetation. Lowest population densities have occurred in small, open sites where shrubs or trees were present, or in the furrows between bedding rows in some pine plantations (Keppner and Keppner 2005). When encountered in dense titi (*Cyrilla racemiflora* and *Cliftonia monophylla*) swamps, the species was associated with temporarily inundated areas open to the sun with some herbaceous vegetation. Such sites may be considered secondary or suboptimal habitat for the species. On sites where mixed habitat features are present (*e.g.,* partially wooded sites or sites with permanent, deep-water ponds), the Panama City crayfish appears to select favorable areas dominated by herbaceous vegetation, with shallow or fluctuating water levels (FWC 2016, p. 3; Keppner and Keppner 2005).

The Panama City crayfish relies on particular soil types for burrow construction and supporting the herbaceous vegetation; these soil types are categorized as core or secondary soils. Core soils provide the best substrate to support the species; secondary soils are less ideal but still used. The core and secondary soil types that support Panama City crayfish within the species' known range are described in more detail in the SSA report (Service 2019, pp. 23–24).

Panama City crayfish build burrows for shelter, which are normally in or adjacent to surface water when it is present on the hydric soils they inhabit (Hobbs 1981). They construct burrows that contact the water table as the surface water of their habitat recedes, and they occupy burrows when surface water is absent or during periods of extreme water temperatures. They emerge from the burrows when surface water is present again or water temperatures are favorable. It appears that they can survive significant periods of drought in their burrows when they can maintain contact with the water table. During these dry periods, the Panama City crayfish excavates and lives in unbranched burrows up to 3 feet long that extend down to the water table, thereby enabling the species to remain adequately hydrated and survive (FWC 2016, p. 3).

Little is known about the specific feeding habits of the Panama City crayfish. Observations on Panama City crayfish that were held in aquaria spanning 1.5 plus years (Keppner 2014, entire) indicate that they are detritivores and herbivores. Specimens were offered dead animal material, but they avoided it in favor of processing the substrate for particles of prepared fish food and the fresh aquatic vegetation that were provided as primary food sources. Herbaceous vegetation likely serves as a food source for the Panama City crayfish.

The Panama City crayfish historically ranged throughout south-central Bay County, Florida, within a 56-square-mile area (see figure, below). The historical range likely created one population connected by core and secondary soils. As urban growth came to Panama City, the range became fragmented and isolated patches. Today, the species has 12 localized populations that can be divided into two distinct

groups: The western and eastern group. The western group includes eight populations, and the eastern group includes four populations. The 12 populations are described in more detail in the SSA report (Service 2019, pp. 37–52), and are referred to as 19th Street, Old Airport, 390 West, Talkington, Minnesota, Edwards, Transmitter West, College Point, Deer Point, High Point, Star, and Transmitter East.

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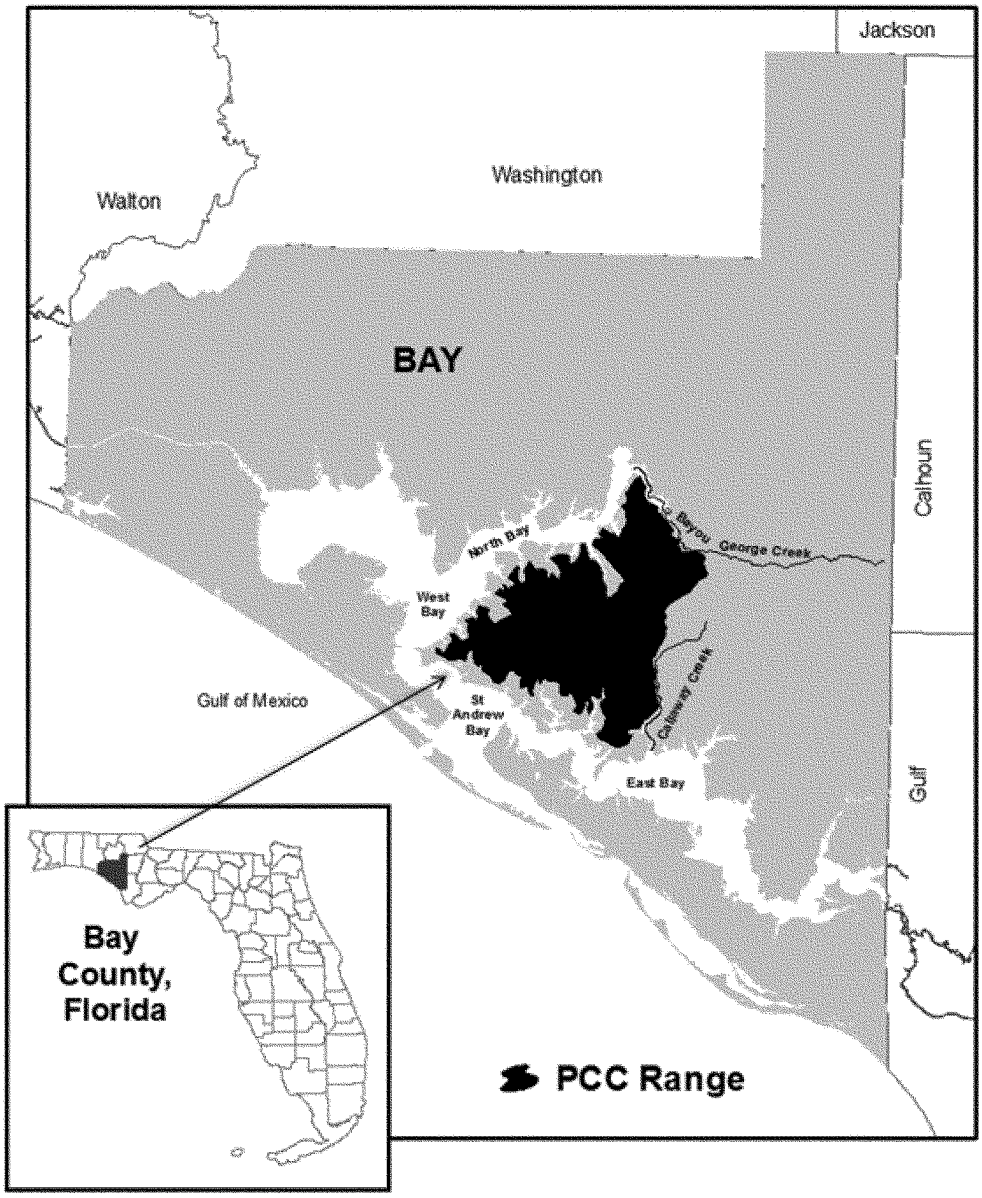

Figure: Range of the Panama City crayfish.

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Conservation Strategy

We developed a conservation strategy for Panama City crayfish to identify critical conservation needs (Service 2017, entire). In this conservation strategy, we rely on the known persistence over time of small populations and published meta-analysis (Traill 2007, entire) to estimate that 2,200 acres of actively managed habitat permanently protected and managed within at least seven population units should ensure the Panama City crayfish remains viable for the foreseeable future. This acreage amount is based on a minimum viable population size (MVP) for Panama City crayfish of 5,137 individuals.

Applying the MVP of 5,137 individuals to an estimate of Panama City crayfish population density gives us an estimate of the minimum viable habitat area required to support highly resilient crayfish populations. Thus far, our estimated population sizes at three sites (19th Street, Transmitter West, Talkington) have ranged from 34 to 623 Panama City crayfish in overall habitat areas ranging from 3 to 232 acres (1.2 to 93.9 hectares). Population estimates ranged from 3 to 9 crayfish per acre, which would equate to 6,600 to 19,800 Panama City crayfish if applied across the currently occupied range of the species.

The Panama City crayfish needs multiple resilient populations spread

across its range to avoid extinction, although how much redundancy among populations is often uncertain. We currently estimate that 2,200 acres (890 hectares) of permanently protected Panama City crayfish habitat would sustain the viability of multiple (up to 7) populations depending on habitat quality. We estimate that protecting at least four large core populations with between 200 and 800 acres (81 and 324 hectares) within each population, in addition to three smaller populations (less than 200 acres (81 hectares) in size), to be managed with fire or mowing every 2 to 3 years, along with a plan to restore existing conservation easements that have suitable soils for the crayfish will sustain the crayfish into the future (Service 2017, entire). While additional field studies should help to refine this estimate, we determined the conservation goal of 2,200 acres that are permanently protected (890 hectares) would support Panama City crayfish for the foreseeable future. However, at this time, agreements are not in place to ensure the necessary protections, and we do not have certainty about whether and where, or in what configuration, those protections may occur on the landscape.

New Information Regarding Species Status Assessment

On January 3, 2018, we proposed to list the Panama City crayfish as a threatened species (83 FR 330). We accepted comments on the proposal for 60 days, ending on March 5, 2018. Based on information we received during the public comment period, we revised the analysis in our SSA report (version 2.0, Service 2019, entire). See Appendix IV of the report for details regarding the changes made from version 1.1 to version 2.0 (Service 2019, p. 114). Notably, new genetic information was incorporated into the analysis resulting in the 231-north population being combined with the Star population because they were found to be not genetically distinct; that combined population is now referred to as the Star Avenue population (Duncan et al. 2017, entire). In addition, several of the names of the populations were modified to better reflect location information.

Based on comments received, the current condition analysis was revised to adjust population factors and add information on mark-recapture population estimates. Additionally, the habitat ranking analysis was revised based on information provided during peer review, resulting in revised current habitat conditions for several of the populations (Service 2019, pp. 61–62).

Subsequent to the proposed listing, Hurricane Michael made landfall in Panama City, Florida, on October 10, 2018. A quick assessment was conducted a few weeks post-storm by the Florida Fish and Wildlife Commission (FWC) (FWC 2018, entire), noting downed trees and difficulty for mowing maintenance activities in Panama City crayfish habitats. Power outages from the storm necessitated use of heavy equipment in powerline habitat areas, resulting in extensive rutting and soil compaction in Panama City crayfish habitat. Despite widespread impacts to many areas post-storm, preliminary mark-recapture survey efforts did not show any reduction in Panama City crayfish population size estimates compared to pre-storm estimates.

The future condition tables and subsequent interpretations were revised based on new analysis (Service 2019, pp. 79–93). In summary, the overall estimate of the Panama City crayfish's resiliency remains low across the majority of its geographic range, particularly in the urbanized western portion. As a result, Panama City crayfish may become extirpated from the vast majority of its range. Future development will likely result in low resiliency, redundancy, and representation across 70 percent of the species' range by 2030. However, as described below, if the remainder (*i.e.,* eastern portion) is protected from development and conservation efforts are focused in the less developed habitat areas, the species is predicted to sustain populations in the wild for the foreseeable future. The most notable revision to the SSA report is the inclusion of a new conservation scenario for our analysis of future conditions (Service 2019, pp. 93–98). This conservation scenario is based on the conservation strategy that includes permanent protection and management of approximately 2,200 acres (890 hectares) of habitat across seven populations (Service 2017, entire). The predicted outcomes of the conservation scenario are straightforward, with populations with higher resiliency continuing to maintain or have improved resiliency in the future as land management efforts improve. Although anticipated habitat protection and habitat management will not immediately change any of the overall current condition ranks, it should, when coupled with the population management measures agreed to by FWC and the Service, ensure that populations with high resiliency will remain so regardless of future development, which is the primary threat to the Panama City crayfish. Additionally, population management measures (*e.g.,* translocation) detailed in this scenario should improve the genetic health and population size of several managed populations. Finally, improved monitoring and applied research agreed to by the Service and FWC should also improve our knowledge of the status of each population to better adjust management actions as needed in the future.

Bay County staff and staff with the Florida Department of Transportation (FDOT) have taken the initiative to expedite conservation of the Panama City crayfish. These efforts, when merged with a longstanding partnership between the FWC and the Service, provide the potential for a significant change in the outlook on the future status of the Panama City crayfish. The prospect of a large acquisition of land to protect the species from its primary threat of habitat loss through development is being considered by those who have a stake in the conservation of the Panama City crayfish. Along with a variety of habitat management commitments to be implemented by, or with the oversight of, FWC, the Service, and local partners, this could provide a substantial and immediate benefit to a species that is experiencing rapid declines in its small remaining habitat areas.

We have carefully assessed this new scientific and commercial information in light of the past, present, and future threats to the Panama City crayfish. Our analysis of this information indicates that, at the species level, habitat development continues to be the primary factor affecting the Panama City crayfish now and into the future.

Based on our analysis of the species' current and future conditions, we conclude that the population and habitat factors used to determine the resiliency, representation, and redundancy for Panama City crayfish will continue to decline so that it is likely that the species will become in danger of extinction within the foreseeable future throughout its range. Therefore, on the basis of the best available scientific and commercial information, we affirm our proposed listing of the Panama City crayfish as a threatened species in accordance with sections 3(20) and 4(a)(1) of the Act.

Proposed Rule Issued Under Section 4(d) of the Act for the Panama City Crayfish

Background

Section 4(d) of the Act contains two sentences. The first sentence states that the Secretary shall issue such regulations as he deems necessary and advisable to provide for the conservation of species listed as threatened. The U.S. Supreme Court has noted that statutory language like ''necessary and advisable'' demonstrates a large degree of deference to the agency (see *Webster* v. *Doe,* 486 U.S. 592 (1988)). Conservation is defined in the Act to mean the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Additionally, the second sentence of section 4(d) of the Act states that the Secretary may by regulation prohibit with respect to any threatened species any act prohibited under section 9(a)(1), in the case of fish or wildlife, or section 9(a)(2), in the case of plants. Thus, the combination of the two sentences of section 4(d) provides the Secretary with wide latitude of discretion to select and promulgate appropriate regulations tailored to the specific conservation needs of the threatened species. The second sentence grants particularly broad discretion to the Service when adopting the prohibitions under section 9.

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, courts have upheld rules developed under section 4(d) as a valid exercise of agency authority where they prohibited take of threatened wildlife or include a limited taking prohibition (see *Alsea Valley Alliance* v. *Lautenbacher,* 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council* v. *National Marine Fisheries Service,* 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002)). Courts have also upheld 4(d) rules that do not address all of the threats a species faces (see *State of Louisiana* v. *Verity,* 853 F.2d 322 (5th Cir. 1988)). As noted in the legislative history when the Act was initially enacted, ''once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him with regard to the permitted activities for those species. He may, for example, permit taking, but not importation of such species, or he may choose to forbid both taking and importation but allow the transportation of such species'' (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Exercising this authority under the Act's section 4(d), we have developed a proposed rule that is designed to address the Panama City crayfish's specific threats and conservation needs. Although the statute does not require us to make a ''necessary and advisable'' finding with respect to the adoption of specific prohibitions under section 9, we find that this rule as a whole satisfies the requirement in section 4(d) of the Act to issue regulations deemed necessary and advisable to provide for the conservation of the Panama City crayfish. As described in the Summary of Biological Status and Threats section of the proposed listing rule (83 FR 330; January 3, 2018), we concluded that the Panama City crayfish is likely to become in danger of extinction within the foreseeable future primarily due to habitat loss and degradation, habitat fragmentation, and subpopulation isolation due to development.

The provisions of this proposed 4(d) rule would promote conservation of the Panama City crayfish by encouraging management of the landscape in ways that meet the conservation needs of the Panama City crayfish and are consistent with land management considerations. The provisions of this proposed rule are one of many tools that we would use to promote the conservation of the Panama City crayfish. This proposed 4(d) rule would apply only if and when we finalize the listing of the Panama City crayfish as a threatened species.

Provisions of the Proposed 4(d) Rule

This proposed 4(d) rule would provide for the conservation of the Panama City crayfish by prohibiting the following activities, except as otherwise authorized or permitted: Importing or exporting; take; possession and other acts with unlawfully taken specimens; delivering, receiving, transporting, or shipping in interstate or foreign commerce in the course of commercial activity; or selling or offering for sale in interstate or foreign commerce.

Multiple factors are affecting the status of the Panama City crayfish, with the primary threats resulting in habitat loss and degradation, habitat fragmentation, and population isolation. A range of activities have the potential to affect these species, including farming and grazing practices, improper silvicultural practices, creation of roadside ditches, rights-of-way, development of residential or commercial properties, and collection for bait (Service 2019, pp. 65–66). These threats, which are expected to be exacerbated by continued development along with the effects of climate change, were central to our assessment of the future viability of the Panama City crayfish.

Under the Act, ''take'' means to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. Some of these provisions have been further defined in regulations at 50 CFR 17.3. Take can result knowingly or otherwise, by direct and indirect impacts, intentionally or incidentally. Regulating incidental and intentional take would help preserve the species' remaining populations, slow their rate of decline, and decrease synergistic, negative effects from other stressors. Therefore, we propose to prohibit intentional and incidental take of the Panama City crayfish, except for those actions and activities specifically excepted by the 4(d) rule.

We may issue permits to carry out otherwise prohibited activities, including those described above, involving threatened wildlife under certain circumstances. Regulations governing permits for threatened wildlife are codified at 50 CFR 17.32. With regard to threatened wildlife, a permit may be issued for the following purposes: For scientific purposes, to enhance the propagation or survival of the species, for economic hardship, for zoological exhibition, for educational purposes, for incidental taking, or for special purposes consistent with the purposes of the Act. There are also certain statutory exemptions from the prohibitions, which are found in sections 9 and 10 of the Act.

The proposed 4(d) rule would also provide for the conservation of the species by allowing exceptions to actions and activities that, while they may have some minimal level of disturbance or take to the Panama City crayfish, are not expected to rise to the level that would negatively impact the species' conservation and recovery efforts. The proposed exceptions to these prohibitions include conservation efforts by the Service or State wildlife agencies, and certain development practices, select land management activities, and some utility actions (described below) that are expected to have negligible impacts to the Panama City crayfish and its habitat.

The first exception is for conservation and restoration efforts for listed species by the Service or State wildlife agencies, including, but not limited to, collection of broodstock, tissue collection for genetic analysis, captive propagation, and subsequent stocking into unoccupied areas within the historical range of the species, and follow-up

monitoring. The proposed 4(d) rule would allow take of the Panama City crayfish without a permit by any employee or agent of the Service or a State conservation agency designated by the agency for such purposes and when acting in the course of their official duties if such action is necessary to aid a sick, injured, or orphaned specimen; to dispose of a dead specimen; or to salvage a dead specimen which may be useful for scientific study.

We recognize our special and unique relationship with our State natural resource agency partners in contributing to conservation of listed species. State agencies often possess scientific data and valuable expertise on the status and distribution of endangered, threatened, and candidate species of wildlife and plants. State agencies, because of their authorities and their close working relationships with local governments and landowners, are in a unique position to assist the Services in implementing all aspects of the Act. In this regard, section 6 of the Act provides that the Services shall cooperate to the maximum extent practicable with the States in carrying out programs authorized by the Act. Therefore, any qualified employee or agent of a State conservation agency that is a party to a cooperative agreement with the Service in accordance with section 6(c) of the Act, who is designated by his or her agency for such purposes, would be able to conduct activities designed to conserve the Panama City crayfish that may result in otherwise prohibited take without additional authorization. In addition, Federal and State wildlife law enforcement officers, working in coordination with Service field office personnel, may possess, deliver, carry, transport, or ship Panama City crayfish taken in violation of the Act as necessary.

The second exception is for certain development activities that will have negligible or beneficial effects on the Panama City crayfish and its habitat, including: Maintenance of existing structures and construction or reconstruction activities that occur within the existing footprint of previously developed areas; new structures that occur within 100 feet of existing structures on an individual private landowner's property and with a new footprint less than 1,000 square feet (ft^2), such as a pool or shed associated with an existing house; culvert installations for individual landowners not associated with larger developments; installation of platforms or boardwalks for recreational purposes on conservation lands that allow sunlight of sufficient levels to maintain herbaceous groundcover; and paths used for nonmotorized activities as long as the project footprint, including construction impacts, impacts no more than 5 percent of the acreage in core or secondary soils within properties under a conservation easement.

The third exception is for select land management activities related to silvicultural (forestry) activities and invasive species control that help maintain habitat for Panama City crayfish and agricultural maintenance activities, that have de minimus effects. Silviculture activities within secondary soils including tree thinning, harvest (including clearcutting), site preparation, planting, and replanting following state best management practices (BMPs) (FDACS 2008, entire) are excepted as the species has persisted in lands under timber management where native groundcover species recolonize naturally. Prescribed burning, wildfire control efforts, herbicide applications targeting exotic plants or shrub species are excepted when following all other state and federal BMPs or permits associated with these actions. Finally, agricultural maintenance activities in pasture and rangelands (including cattle operations) that were established prior to publication of the proposed listing rule (January 3, 2018) that do not have indirect impacts to adjacent Panama City crayfish habitat will be excepted.

The fourth exception is for some utility actions that are expected to have minimal impacts to the Panama City crayfish or its habitat. These include ditch mowing and maintenance activities outside of critical habitat units, or ditch mowing and maintenance within critical habitat units after coordination with the local FWS office. Culvert replacements or maintenance that do not adversely affect, but improve or restore, the natural hydrology are excepted. In coordination with the local FWS office, the following are excepted: Maintenance of rights-of-way, powerline and pole placements and replacements, and directional boring by utility owners.

We reiterate that these actions and activities may have some minimal level of take of the Panama City crayfish, but any such take is expected to be rare and insignificant, and is not expected to negatively impact the species' conservation and recovery efforts. We expect the restoration activities to have a net beneficial effect on the species. Across the species' range, habitat has been degraded and fragmented by development and land use changes. The habitat restoration activities in the proposed 4(d) rule are intended to improve habitat conditions for the species in the long term.

Nothing in this proposed 4(d) rule would change in any way the recovery planning provisions of section 4(f) of the Act, the consultation requirements under section 7 of the Act, or the ability of the Service to enter into partnerships for the management and protection of the Panama City crayfish. However, interagency cooperation may be further streamlined through planned programmatic consultations for the species between Federal agencies and the Service, where appropriate. We ask the public, particularly State agencies and other interested stakeholders that may be affected by the proposed 4(d) rule, to provide comments and suggestions regarding additional guidance and methods that the Service could provide or use, respectively, to streamline the implementation of this proposed 4(d) rule (see Information Requested, above).

Proposed Critical Habitat Determination

Background

Critical habitat is defined in section 3 of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features.

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and

procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that Federal agencies ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Designation also does not allow the government or public to access private lands, nor does designation require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Where a landowner requests Federal agency funding or authorization for an action that may affect a listed species or critical habitat, the Federal agency would be required to consult with the Service under section 7(a)(2) of the Act. However, even if the Service were to conclude that the proposed activity would result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific and commercial data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat). In identifying those physical or biological features that occur in specific occupied areas, we focus on the specific features that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. When designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied by the species would be inadequate to ensure the conservation of the species. In addition, for an unoccupied area to be considered essential, the Secretary must determine that there is a reasonable certainty both that the area will contribute to the conservation of the species and that the area contains one or more of those physical or biological features essential to the conservation of the species.

Section 4 of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information from the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, and where the species may be present, will continue to be subject to: (1) Conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in section 9 of the Act. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of this species. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans (HCPs), or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

Prudency Determination

Section 4(a)(3) of the Act, as amended, and implementing regulations (50 CFR 424.12) require that, to the maximum extent prudent and determinable, the Secretary shall designate critical habitat at the time the species is determined to be an endangered or threatened species. Our regulations (50 CFR 424.12(a)(1)) state that the Secretary may, but is not required to, determine that a designation would not be prudent in the following circumstances:

(i) The species is threatened by taking or other human activity and

identification of critical habitat can be expected to increase the degree of such threat to the species;

(ii) The present or threatened destruction, modification, or curtailment of a species' habitat or range is not a threat to the species, or threats to the species' habitat stem solely from causes that cannot be addressed through management actions resulting from consultations under section 7(a)(2) of the Act;

(iii) Areas within the jurisdiction of the United States provide no more than negligible conservation value, if any, for a species occurring primarily outside the jurisdiction of the United States;

(iv) No areas meet the definition of critical habitat; or

(v) The Secretary otherwise determines that designation of critical habitat would not be prudent based on the best scientific data available.

As discussed in the January 3, 2018, proposed listing rule (83 FR 330), there is currently no imminent threat of take attributed to collection or vandalism identified under Factor B for this species, and identification and mapping of critical habitat is not expected to initiate any such threat. In our SSA and proposed listing determination for the Panama City crayfish, we determined that the present or threatened destruction, modification, or curtailment of habitat or range is a threat to the Panama City crayfish and that those threats in some way can be addressed by section 7(a)(2) consultation measures. The species occurs wholly in the jurisdiction of the United States, and we are able to identify areas that meet the definition of critical habitat. Therefore, because none of the circumstances enumerated in our regulations at 50 CFR 424.12(a)(1) apply and because there are no other circumstances the Secretary has identified for which this designation of critical habitat would be not prudent, we have determined that the designation of critical habitat is prudent for the Panama City crayfish.

Critical Habitat Determinability

Having determined that designation is prudent, under section 4(a)(3) of the Act we must find whether critical habitat for the Panama City crayfish is determinable. Our regulations at 50 CFR 424.12(a)(2) state that critical habitat is not determinable when one or both of the following situations exist:

(i) Data sufficient to perform required analyses are lacking, or

(ii) The biological needs of the species are not sufficiently well known to identify any area that meets the definition of ''critical habitat.''

When critical habitat is not determinable, the Act allows the Service an additional year to publish a critical habitat designation (16 U.S.C. 1533(b)(6)(C)(ii)).

We reviewed the available information pertaining to the biological needs of the species and habitat characteristics where this species is located. This and other information represent the best scientific data available and led us to conclude that the designation of critical habitat is determinable for the Panama City crayfish.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance. These characteristics are described below for the Panama City crayfish:

(1) Space for individual and population growth and for normal behavior: The Panama City crayfish naturally inhabits shallow, ephemeral, freshwater wetlands that are associated with early successional wet prairie-marsh and wet pine flatwoods and their associated communities. These locations historically supported a native herbaceous plant community dominated by native wetland grasses and sedges with an accompanying overstory of no to low-density pines and were naturally maintained by periodic wildfire.

(2) Food, water, air, light, minerals, or other nutritional or physiological requirements: Native herbaceous vegetation is important to the Panama City crayfish for food, detritus formation, and cover. Absence of vegetation increases exposure of this small crayfish to predation and reduced availability of food. Although Panama City crayfish are facultative air breathers, moisture is required to facilitate the respiratory process. Burrowing to groundwater or access to surface water are both important habitat features needed to prevent desiccation of individuals and populations. The Panama City crayfish cannot burrow much deeper than 3 feet below the surface and prefer surface waters less than 1 foot deep (E.Keppner 2003, pers. comm.).

(3) Cover or shelter: The Panama City crayfish relies mostly on herbaceous vegetation that grows on core and secondary soils, which allow them to burrow for shelter and to rear young. The ability to burrow to the water table during times of drought is essential to the persistence of the species. Core soils have depth to water tables that meet the depth threshold that is important for long-term Panama City crayfish population persistence. These core soils provide the sediment structure needed for burrow construction to the water table and also support the herbaceous

vegetation upon which the species relies for food and cover. Young crayfish are often captured clinging to vegetation in emergent, yet shallow, water bodies.

Secondary soil types are drier, and it is believed the species cannot persist when only secondary soils are available with below-average water tables. They are mentioned here because they may support Panama City crayfish after recent rainfalls and longer periods of time after above-average rainfall that influences water table depths, and they may provide connectivity between two patches of core soils. Ninety-six percent of known occurrences of Panama City crayfish occur within either core soils or within secondary soils that are within 100 meters (328 feet) of core soils. These secondary soils also provide the sediment structure needed for burrow construction to the water table and also support the herbaceous vegetation upon which the species relies for food and cover except during times of drought.

(4) Sites for breeding, reproduction, or rearing (or development) of offspring: Shelters, such as burrows, are an important resource for crayfish as they provide for protection from predation and space for mating and for rearing hatchlings. Burrows also help to maintain hydration and preferred body temperatures. Surface waters provide shelter for juveniles to grow prior to being large enough to burrow. These surface water locations also provide for breeding and feeding grounds. Surface water must be sufficiently deep, but usually less than 1 foot (0.3 meters) deep, to support the species but shallow enough to sustain herbaceous vegetation. Waters greater than 1 foot (0.3 meters) deep sustain other crayfish species that may outcompete the Panama City crayfish.

(5) Habitats that are protected from disturbance or are representative of the historical, geographical, and ecological distributions of a species: The Panama City crayfish's historical range is estimated to cover a 56-square-mile area (Service 2019, entire). Hardwood swamps fall within the core soil category but are not actually suitable for the Panama City crayfish (except the transition edge habitat). Land acreages within the Panama City crayfish's range total 35,658 acres, with a composition of the following soils: (1) Core with 14,880 acres (6,022 hectares; 42 percent of the land area); (2) secondary with 12,379 acres (5,010 hectares; 35 percent of the land area), and (3) unsuitable soils with 8,399 acres (3,399 hectares; 23 percent of the land area). We estimate that approximately 9,180 acres (3,715 hectares) of core and 5,647 acres (2,285 hectares) of secondary soils remain undeveloped (using 2016 data) and are therefore suitable for the Panama City crayfish. We estimate that 3,606 acres (1,459 hectares) of the core (3,242 acres (1,312 hectares, or 22 percent)) and secondary (364 acres (147 hectares, or 3 percent)) soils are hardwood swamp, which are not directly used by the Panama City crayfish but are included within acreage totals because they provide transition habitat.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of the Panama City crayfish from studies of this species' habitat, ecology, and life history as described above. Additional information can be found in the proposed listing rule published in the **Federal Register** on January 3, 2018 (83 FR 330), and the Panama City Crayfish SSA report (version 2.0; Service 2019, entire). We have determined that the following physical or biological features are essential to the conservation of the Panama City crayfish:

(1) Undeveloped lands, including cropland, utilities rights-of-way, timberlands, or grazing lands, that support open wet pine flatwoods and wet prairie habitats that contain the following:

(a) Appropriate herbaceous groundcover vegetation;

(b) Permanent or temporary pools of shallow (usually less than 1 foot) freshwater locations; and

(c) Gently-sloped ground level swales with a 3:1 or shallower slope ratio along ecotonal or transitional areas.

(2) Soil types within undeveloped lands that provide sediment structure needed for burrow construction and that support some native herbaceous vegetation and the likelihood of native seed bank that with management will provide vegetation needed for additional food and cover, and where the ground water is always within 3 feet of the ground surface and surface waters occur on occasion. These soil types include:

(a) Core soils for Panama City crayfish, including (note: prefix numbers refer to map units in the Soil Survey for Bay County, Florida (USDA 1984, entire)): (22) Pamlico-Dorovan Complex, (29) Rutlege Sand, (32) Plummer Sand, (33) Pelham Sand, (39) Pantego Sandy Loam, and (51) Rutledge-Pamlico Complex;

(b) Secondary soils within 100 meters (328 feet) of core soils: (1) Albany Sand, (12) Leefield Sand, (13) Leon Fine Sand, (31) Osier Fine Sand, and (36) Alapaha Loamy Sand; and

(c) Soils that support native herbaceous vegetation such as, but not limited to, wiregrass (*Aristida beyrichiana*), redroot (*Lachnanthes caroliniana*), beakrushes (*Rhynchospora* spp.), pitcher plants (*Sarracenia* spp.), sundews (*Drosera* spp.), butterworts (*Pinguicula* spp.), and lilies (*Hymenocallis* spp.).

(3) Undeveloped lands that contain surface and groundwater of sufficient quality to support all life stages of the Panama City crayfish and the herbaceous vegetation on which they rely. This includes surface waters with:

(a) Oxygen levels that range between 2 and 9 milligrams per liter;

(b) pH levels between 4.1 and 9.2; and

(c) Temperatures between 42 and 94 degrees Fahrenheit (°F) (5 and 34.4 degrees Celsius (°C)), although optimum temperatures are thought to be in the range of 68 to 79 °F (20 to 26 °C) (Butler et al. 2003).

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of this species may require special management considerations or protection to reduce the following threats: Habitat loss and destruction due to residential and commercial development, as well as habitat loss due to changes in the natural disturbance and hydrological regimes that maintain the wet prairie and flatwoods that Panama City crayfish originally inhabited. Historically, the Panama City crayfish inhabited natural and often temporary bodies of shallow fresh water within open pine flatwoods and prairie-marsh communities (as described in the SSA report (version 2.0; Service 2019, p. 56)). However, most of these communities have been cleared for residential or commercial development or replaced with slash pine (Pinus elliottii) plantations. Thus, the Panama City crayfish currently is known to inhabit the waters of grassy, gently-sloped ditches and swales; furrows within slash pine plantations; and utility rights-of-way.

Special management considerations or protections are required within critical habitat areas to address these habitat loss and destruction threats. The occupied units we are proposing to designate as critical habitat for Panama City crayfish will require some level of

management to address the current and future threats to the physical or biological features. Management activities that could ameliorate these threats include (but are not limited to): (1) Protection of lands from development through purchase, easement, or other conservation agreements that will prevent permanent conversion of Panama City crayfish habitat to other land uses; and (2) restoration and management of habitat to maintain the appropriate vegetative and hydrological characteristics for the Panama City crayfish.

These management activities will protect the physical or biological features for the species by protecting currently suitable habitat from being converted to other land uses and by promoting the appropriate vegetative and hydrological characteristics that the Panama City crayfish needs for survival. Additionally, management of habitat to protect the physical or biological features on occupied critical habitat will help achieve recovery of the Panama City crayfish.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), when designating critical habitat, the Secretary will first evaluate areas occupied by the species. The Secretary will only consider unoccupied areas to be essential where a critical habitat designation limited to geographical areas occupied would be inadequate to ensure the conservation of the species. We are not currently proposing to designate any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that meet the definition of critical habitat and because occupied areas are sufficient to ensure the conservation of the species.

We reviewed available information that pertains to the habitat requirements of this species using information that was cited within the SSA report (Service 2019, entire) and information presented in the Service's conservation strategy for Panama City crayfish critical conservation needs (Service 2017, entire); sources of information on habitat requirements include existing State management plans, endangered species reports, studies conducted at occupied sites and published in peer-reviewed articles, agency reports, and data collected during monitoring efforts (Service 2019, entire). Based on known occurrences and habitat requirements, critical habitat units were mapped in ArcMap (ESRI, Inc.) using the U.S. Department of Agriculture, Natural Resources Conservation Service, Soil Survey Geographic Database (USDA 2019, unpaginated). ArcGIS software was used to calculate the acreage of core and secondary soils within the historical range of the Panama City crayfish prior to anthropogenic habitat disturbances. Core soil types (as described in *Species Description* in the proposed listing rule (83 FR 330, January 3, 2018, pp. 332–333) and in *Physical or Biological Features Essential to the Conservation of the Species,* above) were buffered by 100 meters. We used 100 meters as our buffer because we found that 96 percent of known occurrences of Panama City crayfish occur within 100 meters of core soils and this buffer encompasses the secondary soil types (as described in *Species Description* in the proposed listing rule (83 FR 330, January 3, 2018, pp. 332–333) and in *Physical or Biological Features Essential to the Conservation of the Species,* above). In geographic information systems (GIS) mapping, the buffered soils were spatially processed by clipping to the population buffer of one-quarter mile, and developed areas were excluded based on 2016 Florida Department of Transportation aerial imagery (FDOT 2016, unpaginated).

In summary, for areas within the geographic area occupied by the species at the time of listing and with sufficient availability of land, we delineate critical habitat unit boundaries using the following criteria:

(1) Suitable habitat surrounding each of 10 known populations of Panama City crayfish, delineated by polygons using one-quarter mile (0.4 kilometer (km)) circles around sample points with known species occurrences, based on the movement patterns of small crayfishes (**Note:** Habitat surrounding two populations was not included for critical habitat designation, as explained below);

(2) Core and secondary soils within 100 meters (328 feet) of core soils that contain one or more of the physical or biological features to support life-history functions essential for conservation of the Panama City crayfish.

Hardwood swamps found within core soils are considered unsuitable for the crayfish, and this habitat type was removed to the maximum extent possible.

The total acreage calculated for critical habitat based upon the above criteria amounted to 7,177 acres (2,904 hectares). Accordingly, we propose to designate as critical habitat those areas that contain the physical and biological features essential to the Panama City crayfish and that are currently occupied by the species.

For the purposes of critical habitat designation, we determined a unit to be occupied if it contains recent (*i.e.,* observed since 2015) observations of Panama City crayfish. The proposed critical habitat designation does not include all lands known to have been occupied by the species historically; instead, it focuses on currently occupied lands that have retained the necessary physical or biological features that will allow for the maintenance and expansion of existing populations. The following locations (*i.e.,* populations as defined in the SSA) meet the definition of areas occupied by the species at the time of listing and that present sufficient availability of lands to support a population: 19th Street, Talkington, Minnesota, Transmitter West, Deer Point, High Point, Star, and Transmitter East. College Point and Old Airport populations were not consistently occupied, nor was there sufficient suitable habitat within the one-quarter-mile (0.4-km) polygon to support recovery, and these populations, therefore, are not included in the proposed designation. We also do not include Edwards, a population representing an original collection site from 1942, nor 390 West given the fragmentation of that population by the industrial park resulted in too little remaining habitat to support a viable population over time. While both areas are still occupied by Panama City crayfish, Edwards is surrounded by industrial buildings and bordered by U.S. Route 231 on its west edge, and 390 West will soon be bisected by a four-lane highway as it is currently under construction. Potential habitat for recovery in either of these locations is limited and potentially fragmented. Long-term management will be challenging given proximity to major roadways and industrial development. As mentioned above, we exclude developed areas within the proposed designation to the extent possible in the mapping exercise and in the text of the rule, as explained below. Designating critical habitat in these eight occupied areas of the Panama City crayfish would sufficiently conserve the species, leading to its recovery.

We are not proposing to designate any areas outside the geographical area occupied by the species because we have not identified any unoccupied areas that are essential to the conservation of the species. In addition, based on our conservation strategy, the

protection of the eight occupied units (as further described below) are sufficient for the conservation of the species.

When determining proposed critical habitat boundaries, we made every effort to avoid including developed areas such as lands covered by buildings, pavement, and other structures because such lands lack physical or biological features necessary for the Panama City crayfish. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this proposed rule have been excluded by text in the proposed rule and are not proposed for designation as critical habitat. Therefore, if the critical habitat is finalized as proposed, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

We propose to designate as critical habitat lands that we have determined are occupied at the time of listing (*i.e.,* currently occupied) and that contain one or more of the physical or biological features that are essential to support life-history processes of the species.

Units are proposed for designation based on one or more of the physical or biological features being present to support Panama City crayfish's life-history processes. All units contain all of the identified physical or biological features and support multiple life-history processes.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Proposed Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the shapefiles on which each map is based available to the public on *http://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0137, on our internet site *http://ecos.fws.gov,* and at the Florida Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Proposed Critical Habitat Designation

We are proposing eight units as critical habitat for the Panama City crayfish. The critical habitat units we describe below constitute our assessment based on the best available science of areas that meet the definition of critical habitat for the Panama City crayfish. In total, they comprise 7,177 acres (2,904 hectares) of land, entirely within Bay County, Florida. The table below summarizes the approximate area and ownership of the units, which are described in detail below.

TABLE OF PROPOSED CRITICAL HABITAT UNITS FOR THE PANAMA CITY CRAYFISH

Group	Unit	Unit name	Occupied	Land ownership (AC.)		Total proposed critical habitat area (AC.)	Percent of total (%)
				Private	State/Local		
Western	1	19th Street	Yes	20.6	3.7	24.3	0
	2	Talkington	Yes	53.1	0.0	53.1	1
	3	Minnesota	Yes	27.9	37.2	65.0	1
	4	Transmitter West	Yes	243.7	4.7	248.4	3
Eastern	5	Deer Point	Yes	413.8	0.9	414.6	6
	6	High Point	Yes	37.9	0.5	38.4	1
	7	Star	Yes	2,751.6	9.7	2,761.4	38
	8	Transmitter East	Yes	3,489.0	82.5	3,571.5	50
Total				7,037.6	139.2	7,176.8	100
Percent of total				98%	2%	100%	

Note: Area estimates reflect all land within critical habitat unit boundaries; Area sizes may not sum due to rounding.

The eight units we propose as critical habitat are broken into two groups, based on the western (Units 1 through 4) and eastern (Units 5 through 8) groups described in the SSA report (Service 2019, pp. 37–52). These two groups are distinguished by east-west genetic differentiation based on proximity to other populations and amounts of fragmentation within a population polygon. Below we describe each unit, and reasons why they meet the definition of critical habitat for the Panama City crayfish.

Western Group

The western group is comprised of four units supporting geographically isolated populations scattered throughout the species' range primarily in the cities of Panama City and Lynn Haven in Bay County, Florida. The Service proposes designation of 390.8 acres (158.2 hectares) in total for the western group. These populations have been isolated by residential and commercial development, which resulted in habitat loss and fragmentation. These populations are currently supported by an average of 83.4 acres (33.8 hectares) of habitat (range 24.3–248.4 acres (9.8–100.5 hectares)). However, the Transmitter West population is by far the largest at 248.4 acres (100.5 hectares), and this population may have historically been a critical link both genetically and geographically between the western and eastern representative groups. The remaining three populations are supported by an average of 50.3 acres (20.4 hectares) (range 24.3–65.0 acres (9.8–26.3 hectares)). Limited habitat area needed to support each population and lack of habitat connectivity to other populations in this group are the greatest management challenges.

Unit 1: 19th Street

The 19th Street population is the southwestern-most population located off 19th Street in Panama City, Florida. It is located on both sides of an active railroad track with habitat totaling 24.3 acres (9.8 hectares). Land ownership is mostly private, but some is in public ownership with 3.7 acres (1.5 hectares) owned by Bay County. Only secondary soils remain undeveloped, but the elevated railroad track has artificially provided a water barrier, often keeping the site ponded when all others have dried up. Maintenance (*i.e.,* mowing and woody vegetation removal) for the railroad has kept the adjacent right-of-way covered in dense, herbaceous

vegetation that is ideal for the Panama City crayfish. Adjacent unmanaged slash pine stands, where burrows have been documented, and a mowed grass field also provide habitat.

Panama City crayfish occurrence was documented in 2001, 2012–2014, and 2016–2018. All of the essential physical or biological features are found within the unit. The essential features (*e.g.,* appropriate herbaceous groundcover vegetation and permanent or temporary pools of shallow fresh water) for this unit may require special management, particularly mowing, to ensure maintenance or improvement of the existing habitat.

Unit 2: Talkington

The Talkington population is located off of Jenks Avenue in Panama City, Florida, with habitat totaling 53.1 acres (21.5 hectares). Land ownership is entirely private, although 10 acres (4 hectares) is under easement for conservation. The Talkington Family Nature Preserve forms the centerpiece of this population, with land ownership held by the Bay County Conservancy (BCC), and the associated conservation easement held by Florida Department of Environmental Protection (FDEP). The preserve is primarily pine flatwoods with a cluster of pond pine trees in the center portion. The Service and FWC have a management agreement in place with BCC that allows for mowing to manage the habitat on a 2- to 3-year interval, to mimic the natural fire regime and maintain ideal conditions for the Panama City crayfish. The remaining 43.1 acres (17.4 hectares) of core and secondary soils in the vicinity provide opportunity for additional land protections and management, although much of this area would require restoration of vegetation.

Panama City crayfish occurrence was documented in 2000, 2001, 2003, 2006, 2012, 2013, and 2016–2018. All essential physical and biological features are found within the unit. The essential features, especially appropriate herbaceous groundcover vegetation and permanent or temporary pools of shallow fresh water, for this unit may require special management; establishment of sloped swales and removal of dense shrub thickets would improve conditions for the Panama City crayfish in this unit.

Unit 3: Minnesota

The Minnesota population is located off Minnesota Avenue in Lynn Haven, Florida, with undeveloped habitat totaling 65.0 acres (26.3 hectares). Land ownership is a mix of private and public, and some area is under easement for conservation. This site is largely hardwood-cypress swamp with some possibilities for improving the habitat along 6 acres (2.4 hectares) near and adjacent to the swamp ecotone. The City of Lynn Haven owns 37.2 acres (15.1 hectares), which is under a conservation easement held by FDEP.

The Service and FWC have a management agreement with the City of Lynn Haven that allows the agencies to manage the property when funding is available. Minimal actions have occurred to date to remove some of the pine canopy layer. Other core and secondary soils surrounding the easement consist of dense slash pine plantations. The property has deep rutting from off-road vehicles, horses, and heavy equipment, which may affect the hydrology of the habitat.

Panama City crayfish occurrence was documented in 2015 and 2016. All essential physical and biological features are found within the unit. Achieving the right mosaic of water and grasses requires special management.

Unit 4: Transmitter West

The Transmitter West population is located off Transmitter Road in Lynn Haven and Panama City, Florida, with habitat totaling 248.4 acres (100.5 hectares). Land ownership is a mix of private and public, with approximately 40 percent under easement for conservation. The FDEP holds multiple conservation easements for private landowners with a total 100.5 acres (40.7 hectares) of pine flatwoods. The easements are managed as required by permit with either mowing or burning, and are in good condition for the Panama City crayfish. The remaining habitats, including the 4.7 acres (1.9 hectares) in public ownership owned by the City of Lynn Haven and Bay County, are in mixed condition and in need of regular management (*e.g.,* prescribed fire or mowing).

Panama City crayfish occurrence was documented in 2004, 2013, and 2016. All essential physical and biological features are found within the unit, with grasses maintained by fire in the past and mowing more recently. Different depths of water bodies occur that provide a mosaic of water features with herbaceous grasses to make this a good area for the Panama City crayfish. Management is required to reduce encroaching shrubs and to remove tree debris caused by Hurricane Michael in October 2018.

Eastern Group

The eastern group is comprised of four units supporting populations scattered throughout the species' range primarily in the unincorporated portions of Bay County, Florida. The Service proposes designation of 6,785.9 acres (2,746.2 hectares) in total for the eastern group. These populations are currently supported by an average of 1,696.5 acres (686.5 hectares) of habitat (range 38.4–3,571.5 acres (15.5–1,445.3 hectares)). However, the Star and Transmitter East populations are the largest at 2,761.4 and 3,571.5 acres (1,117.5 and 1,445.3 hectares), respectively. These two populations represent the largest connected blocks of core and secondary soils with appropriate vegetation. Although the vegetation and hydrology have been altered from native wet prairie and pine flatwoods habitats by silvicultural and agricultural uses, the geographic extent of these two populations forms the basis for the species' long-term resilience.

Unit 5: Deer Point

The Deer Point population occurs on a peninsula located near Bay County Road 2321 in Lynn Haven and Panama City, Florida, and is supported by 414.6 acres (167.8 hectares) of habitat. The land is bordered by Willams Bayou on the northeast, Mill Bayou on the southwest, and North Bay to the north. Land ownership is almost entirely private, although some areas under easement for conservation. Only 0.9 acres (0.4 hectares) is in public ownership by Bay County.

Four privately owned easements lie within or are adjacent to areas included in this unit. These easements protect 95.0 acres (38.4 hectares) of core and secondary soil habitat, although some of the secondary soil habitats do not meet the criteria for inclusion within critical habitat due to distance from core soils. The Trust for Public Lands holds 90.0 acres (36.4 hectares) under easement, but that easement is to be transferred to the City of Lynn Haven in the near future. FDEP holds three easements totaling 35.0 acres (14.2 hectares) that are still owned by a private landowner (D&H Properties, LLC). The Service and FWC hold a management agreement with D&H Properties, LLC, and have mowed and burned 24.0 acres (9.7 hectares) of this 35.0-acre (14.2-hectare) property that are held in easements by FDEP. The remaining habitat is on lands that are heavily timbered and unmanaged, resulting in dense overgrowth of titi and slash pine, and hydrology may be affected by these activities as well as borrow pits and dirt roads that traverse the unit. Only the portions of these easements that meet the criteria are included as critical habitat. All need regular management,

especially the lands with dense vegetation, for the crayfish to thrive.

Panama City crayfish occurrence was documented on easement lands in 2012 and 2014–2018. All of the essential physical or biological features are found within the unit. Herbaceous groundcover is spotty, and shallow pools of water are small and unreliable, often caused by vehicle tracks, and too deep for Panama City crayfish. Management is required to remove Hurricane Michael tree debris. Considerations on whether there are ways to improve the hydrology are also warranted.

Unit 6: High Point

The High Point population is the northern-most population and is located off Bay County Road 2311 in Bay County, Florida. The population is supported by habitat totaling 38.4 acres (15.5 hectares), and land ownership is almost entirely private, with some acreage under easement for conservation. Only 0.5 acres (0.2 hectares) is in public ownership by Bay County. The 11-acre (4.5 hectare) Marjorie's Magical Marsh-Symone's Sanctimonious Swamp conservation easement owned by BCC contains most of the known Panama City crayfish population.

Panama City crayfish occupy 6.0 (2.4 hectares) of the 11-acre (4.5 hectare) easement, which is in the process of being restored by the Service and FWC under a management agreement with BCC. These six acres are being restored to primarily herbaceous vegetation from a more recent dense mixture of titi shrub thicket in the under- and mid-story and slash pines in the overstory, which has lacked fire management. The remaining core and secondary soil habitat surrounding the easement was historically managed for timber but currently contains dense titi with an intermittent slash pine overstory.

Panama City crayfish occurrence was documented in 2010, 2012–2014, and 2015–2017. All essential physical and biological features are found within the unit. This population, albeit small, has herbaceous ground cover vegetation, pools of shallow water, and appropriate slope ratios, but the unit will require management to maintain the groundcover and keep shrubs from encroaching.

Unit 7: Star

A portion of this unit is located north of the intersection of Bay County Road 2321 and U.S. Highway 231 in Bay County, Florida. Land ownership is a mix of private and public. There are no conservation easements in place, but one 1.4-acre (0.6-hectare) parcel is owned by the State of Florida and used by the Florida Highway Patrol. Although the appropriate core and secondary soil habitat exists, the lands that run parallel to the county road are mostly in dense slash pine plantations for timber production with overgrown groundcover. The plantations east of the county road have been harvested recently. This management is sub-optimal for the Panama City crayfish because of the dense overstory canopy, lack of herbaceous ground cover, infrequent (<3 year) fire management, and bedding that may additionally affect the hydrology of the unit.

The remainder of this habitat unit is adjacent and south of U.S. Highway 231. It forms the farthest east-northeast boundary of the species' geographic range in Bay County, Florida. The population is bordered on the west by U.S. Highway 231, the north by Bayou George Creek, and the south by an unnamed tributary of Mill Bayou. These lands are mostly under timber management since the mid-1980s and in various stages of management from recent harvest to dense slash pines with dense titi shrub layers. The current timber management is sub-optimal for Panama City crayfish because of the dense overstory canopy, lack of herbaceous ground cover, infrequent (<3 year) fire management, and bedding that may additionally affect the hydrology of the unit. Land ownership is predominantly private, with only 9.7 acres (3.9 hectares) in public ownership by Bay County. Gulf Power Company manages rights-of-way along 86 acres (34.8 hectares). The Service and FWC have a management agreement with Gulf Power Company incorporating best management practices, primarily regular mowing, that have stimulated herbaceous vegetation as the primary groundcover. Currently a two-lane road, Star Avenue, bisects this population.

The population in the unit is supported by 2,761.4 acres (1,117.5 hectares). Panama City crayfish occurrence was documented in 2001, 2003–2004, 2006, 2012–2013, and 2016. All essential physical and biological features are found within the unit. Intermittent herbaceous groundcover vegetation and temporary pools of shallow water with hardwood swamp ecotone areas do occur, but much management is required to maintain and improve these biological features needed for increased or more connected populations. Much tree debris remains throughout the unit as a result of Hurricane Michael's 2018 impact to the landscape. It is assumed that some debris will be removed from timber company land and on other small tracts of land, but it is unknown at this time what impacts are likely to occur to Panama City crayfish populations as lands are cleared at large-scale levels.

Unit 8: Transmitter East

The Transmitter East population forms the farthest south-southeast boundary of the species' geographic range in Bay County, Florida. The population is bordered on the west by Transmitter Road, the south by U.S. Highway 98 and State Highway 22, the east by Callaway Creek, and the north by an unnamed tributary of Mill Bayou. The population in this unit is supported by 3,571.5 acres (1,445.3 hectares) of habitat, which has been primarily under timber management since the mid-1980s and in various stages of management from recent harvest to dense slash pines with dense titi shrub layers.

The current management regime is sub-optimal for Panama City crayfish because of the dense overstory canopy, lack of herbaceous ground cover, infrequent (<3 year) fire management, and bedding that may additionally affect the hydrology of the unit. Land ownership is predominantly private, with only 82.5 acres (33.4 hectares) in public ownership by the City of Springfield, Bay County, and the State of Florida. Gulf Power Company manages rights-of-way along approximately 114 acres (46.1 hectares) of land that is populated with the Panama City crayfish. The Service and FWC have a management agreement with Gulf Power incorporating best management practices, primarily regular mowing, that have stimulated herbaceous vegetation as the primary groundcover.

Two conservation easements, 11.3 and 7.3 acres (4.6 and 3.0 hectares) in size, are held by FDEP for two separate landowners. Currently, a two-lane road, Star Avenue, bisects this population. Tram Road also bisects the lower third of the area. It is currently a dirt road and there are plans for converting it to a four-lane asphalt road.

Panama City crayfish occurrence was confirmed in 2001, 2002, and 2006, and extensive efforts documented the species in 2003–2004, 2012–2013, and 2016. All essential physical and biological features are found within the unit. Much tree debris, which will require management, remains throughout as a result of Hurricane Michael's 2018 impact to the landscape. It is assumed that some debris will be removed from timber company land and on other small tracts of land, but it is unknown at this time what impacts are likely to occur on the Panama City

crayfish populations as lands are cleared at large-scale levels.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they fund, authorize, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. In addition, section 7(a)(4) of the Act requires Federal agencies to confer with the Service on any agency action which is likely to jeopardize the continued existence of any species proposed to be listed under the Act or result in the destruction or adverse modification of proposed critical habitat.

We published a final rule revising the definition of destruction or adverse modification on August 27, 2019 (84 FR 44976). Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat as a whole for the conservation of a listed species.

If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Examples of actions that are subject to the section 7 consultation process are actions on State, Tribal, local, or private lands that require a Federal permit (such as a permit from the U.S. Army Corps of Engineers under section 404 of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or a permit from the Service under section 10 of the Act) or that involve some other Federal action (such as funding from the Federal Highway Administration, Federal Aviation Administration, or the Federal Emergency Management Agency). Federal actions not affecting listed species or critical habitat and actions on State, Tribal, local, or private lands that are not federally funded, authorized, or carried out by a Federal agency do not require section 7 consultation. Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species and/or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate formal consultation on previously reviewed actions. These requirements apply when the Federal agency has retained discretionary involvement or control over the action (or the agency's discretionary involvement or control is authorized by law) and, subsequent to the previous consultation, we have listed a new species or designated critical habitat that may be affected by the Federal action, the action has been modified in a manner that affects the species or critical habitat in a way not considered in the previous consultation, new information reveals effects of the action may affect the species or critical habitat in a way not previously considered, or incidental take is exceeded. In such situations, Federal agencies sometimes may need to request reinitiation of consultation with us, but the regulations also specify some exceptions to the requirement to reinitiate consultation on specific land management plans after subsequently listing a new species or designating new critical habitat. See the regulations for a description of those exceptions.

Application of the ''Destruction or Adverse Modification'' Standard

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat as a whole for the conservation of the listed species. As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe, in any proposed or final regulation that designates critical habitat, activities involving a Federal action that may violate section 7(a)(2) of the Act by destroying or adversely modifying such habitat, or that may be affected by such designation.

Activities that the Services may, during a consultation under section 7(a)(2) of the Act, find are likely to destroy or adversely modify critical habitat include, but are not limited to:

(1) Actions that would significantly alter hydrological and soil characteristics. Such activities could include, but are not limited to, those that result in wetland fill or draining or, conversely, provide additional waters to the wetland. Activities drying the wetland (via fill or draining) can result in changes in depth to water tables that are less than the depth threshold that is important for long-term Panama City crayfish population persistence. These activities can also alter soils from those that provide the sediment structure needed to allow for burrow construction down to the water table and also support the herbaceous vegetation upon which the species relies for food and cover. Activities providing additional water can allow other crayfish species that persist in deeper waters to outcompete the Panama City crayfish.

(2) Actions that would significantly alter water quality parameters including oxygen content, temperature, and chemical composition. Such activities could include, but are not limited to, release of chemicals, excess nutrients, pesticides, and biological or other pollutants into the surface water or connected groundwater at a point source or by dispersed release (non-point source). These activities could alter water conditions to levels that are beyond the tolerances of the crayfish and result in direct or cumulative adverse effects to these individuals and their life cycles.

(3) Actions that would significantly and permanently alter vegetative characteristics. Such activities could include, but are not limited to, residential and commercial

construction; road construction; and draining, filling or otherwise destroying or altering wetlands. These activities may lead to changes in hydrology and soil characteristics that prevent the appropriate vegetation from growing. These activities can result in an absence or reduced levels of herbaceous vegetation that is important to the Panama City crayfish for food, detritus formation, and cover.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act (16 U.S.C. 1533(a)(3)(B)(i)) provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. There are no DoD lands with a completed INRMP within the proposed critical habitat designation.

Consideration of Exclusions Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, national security impact, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude an area from critical habitat if he determines that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat, unless he determines, based on the best scientific data available, that the failure to designate such area as critical habitat will result in the extinction of the species. In making the determination to exclude a particular area, the plain language of the statute, as well as the legislative history, make clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor.

We describe below the process that we undertook for taking into consideration each category of impacts and our analyses of the relevant impacts.

Consideration of Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. To assess the probable economic impacts of a designation, we must first evaluate specific land uses or activities and projects that may occur in the area of the critical habitat. We then must evaluate the impacts that a specific critical habitat designation may have on restricting or modifying specific land uses or activities for the benefit of the species and its habitat within the areas proposed. We then identify which conservation efforts may be the result of the species being listed under the Act versus those attributed solely to the designation of critical habitat for this particular species. The probable economic impact of a proposed critical habitat designation is analyzed by comparing scenarios both ''with critical habitat'' and ''without critical habitat.''

The ''without critical habitat'' scenario represents the baseline for the analysis, which includes the existing regulatory and socio-economic burden imposed on landowners, managers, or other resource users potentially affected by the designation of critical habitat (*e.g.,* under the Federal listing as well as other Federal, State, and local regulations). The baseline, therefore, represents the costs of all efforts attributable to the listing of the species under the Act (*i.e.,* conservation of the species and its habitat incurred regardless of whether critical habitat is designated). The ''with critical habitat'' scenario describes the incremental impacts associated specifically with the designation of critical habitat for the species. The incremental conservation efforts and associated impacts would not be expected without the designation of critical habitat for the species. In other words, the incremental costs are those attributable solely to the designation of critical habitat, above and beyond the baseline costs. These are the costs we use when evaluating the benefits of inclusion and exclusion of particular areas from the final designation of critical habitat should we choose to conduct a discretionary 4(b)(2) exclusion analysis.

For this particular designation, we developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this proposed designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the designation of critical habitat for the Panama City crayfish (IEC 2018). We began by conducting a screening analysis of the proposed designation of critical habitat in order to focus our analysis on the key factors that are likely to result in incremental economic impacts. The purpose of the screening analysis is to filter out particular geographic areas of critical habitat that are already subject to such protections and are, therefore, unlikely to incur incremental economic impacts. In particular, the screening analysis considers baseline costs (*i.e.,* absent critical habitat designation) and includes probable economic impacts where land and water use may be subject to conservation plans, land management plans, best management practices, or regulations that protect the habitat area as a result of the Federal listing status of the species. Ultimately, the screening analysis allows us to focus our analysis on evaluating the specific areas or sectors that may incur probable incremental economic impacts as a result of the designation. If there are any unoccupied units in the proposed critical habitat designation, the screening analysis assesses whether any additional management or conservation efforts may incur incremental economic impacts. This screening analysis combined with the information contained in our IEM are what we consider our draft economic analysis (DEA) of the proposed critical habitat designation for the Panama City crayfish; our DEA is summarized in the narrative below.

Executive Orders (E.O.s) 12866 and 13563 direct Federal agencies to assess the costs and benefits of available regulatory alternatives in quantitative (to the extent feasible) and qualitative terms. Consistent with the E.O. regulatory analysis requirements, our effects analysis under the Act may take into consideration impacts to both directly and indirectly affected entities, where practicable and reasonable. If sufficient data are available, we assess to the extent practicable the probable impacts to both directly and indirectly affected entities. As part of our screening analysis, we considered the types of economic activities that are likely to occur within the areas likely affected by the critical habitat designation. In our evaluation of the probable incremental economic impacts that may result from the proposed designation of critical habitat for the Panama City crayfish, first we identified, in the IEM dated July 13, 2018, probable incremental economic impacts associated with the following categories of activities: Agriculture, forest management (silviculture, timber), development, recreation, restoration and conservation management activities, transportation, and utilities. We considered each

industry or category individually. Additionally, we considered whether their activities have any Federal involvement. Critical habitat designation generally will not affect activities that do not have any Federal involvement; under the Act, designation of critical habitat only affects activities conducted, funded, permitted, or authorized by Federal agencies. If we finalize our proposal to list the species, in areas where the Panama City crayfish is present, Federal agencies would be required to consult with the Service under section 7 of the Act on activities they fund, permit, or implement that may affect the species. If we finalize this proposed critical habitat designation, consultations to avoid the destruction or adverse modification of critical habitat would be incorporated into the existing consultation process.

In our IEM, we attempted to clarify the distinction between the effects that would result from the species being listed and those attributable to the critical habitat designation (*i.e.,* difference between the jeopardy and adverse modification standards) for the Panama City crayfish's critical habitat. Because the proposed critical habitat for the Panama City crayfish coincides with currently occupied areas by the species, it has been our experience that it is more difficult to discern which conservation efforts are attributable to the species being listed and those which will result solely from the designation of critical habitat. However, the following specific circumstances in this case help to inform our evaluation: (1) The essential physical or biological features identified for critical habitat are the same features essential for the life requisites of the species, and (2) any actions that would result in sufficient harm or harassment to constitute jeopardy to the Panama City crayfish would also likely adversely affect the essential physical or biological features of critical habitat. The IEM outlines our rationale concerning this limited distinction between baseline conservation efforts and incremental impacts of the designation of critical habitat for this species. This evaluation of the incremental effects has been used as the basis to evaluate the probable incremental economic impacts of this proposed designation of critical habitat.

The proposed critical habitat designation for the Panama City crayfish includes eight units, each of which contains one geographically and/or genetically distinct population of the Panama City crayfish. All of these units are in Bay County, Florida, and none occur on Federal lands. For the purposes of critical habitat designation, we determined a unit to be occupied if it contains recent (*i.e.,* observed since 2015) observations of Panama City crayfish. All units are occupied because they contain populations of Panama City crayfish at the time of proposed listing, and each unit is considered essential to the conservation of the species. In total, we are proposing 7,177 acres (2,904 hectares) for designation as critical habitat for the Panama City crayfish. In occupied areas, any actions that may affect the species or its habitat would also affect critical habitat, and it is unlikely that any additional conservation efforts would be recommended to address the adverse modification standard over and above those recommended as necessary to avoid jeopardizing the continued existence of the Panama City crayfish. Incremental costs of the proposed critical habitat designation for the Panama City crayfish are likely to be limited to additional administrative costs to consider adverse modification in consultations in all units. The incremental administrative burden resulting from the designation of critical habitat for the Panama City crayfish is not anticipated to reach an annual effect of $100 million (which is the economic threshold for a ''significant regulatory action'' (see section 3(f)(1) of Executive Order 12866)) based on the anticipated annual number of consultations and associated consultation costs, which are not expected to exceed $60,000 in any year. The designation is unlikely to trigger additional requirements under State or local regulations and is not expected to have perceptional effects.

We are soliciting data and comments from the public on the DEA discussed above, as well as all aspects of this proposed rule and our required determinations. During the development of a final designation, we will consider the information presented in the DEA and any additional information on economic impacts we receive during the public comment period to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19. In particular, we may exclude an area from critical habitat if we determine that the benefits of excluding the area outweigh the benefits of including the area, provided the exclusion will not result in the extinction of this species.

Consideration of National Security Impacts

Section 4(a)(3)(B)(i) of the Act may not cover all DoD lands or areas that pose potential national-security concerns (*e.g.,* a DoD installation that is in the process of revising its INRMP for a newly listed species or a species previously not covered). If a particular area is not covered under section 4(a)(3)(B)(i), national-security or homeland-security concerns are not a factor in the process of determining what areas meet the definition of ''critical habitat.'' Nevertheless, when designating critical habitat under section 4(b)(2), the Service must consider impacts on national security, including homeland security, on lands or areas not covered by section 4(a)(3)(B)(i). Accordingly, we will always consider for exclusion from the designation areas for which DoD, Department of Homeland Security (DHS), or another Federal agency has requested exclusion based on an assertion of national-security or homeland-security concerns.

We cannot, however, automatically exclude requested areas. When DoD, DHS, or another Federal agency requests exclusion from critical habitat on the basis of national-security or homeland-security impacts, it must provide a reasonably specific justification of an incremental impact on national security that would result from the designation of that specific area as critical habitat. That justification could include demonstration of probable impacts, such as impacts to ongoing border-security patrols and surveillance activities, or a delay in training or facility construction, as a result of compliance with section 7(a)(2) of the Act. If the agency requesting the exclusion does not provide us with a reasonably specific justification, we will contact the agency to recommend that it provide a specific justification or clarification of its concerns relative to the probable incremental impact that could result from the designation. If the agency provides a reasonably specific justification, we will defer to the expert judgment of DoD, DHS, or another Federal agency as to: (1) Whether activities on its lands or waters, or its activities on other lands or waters, have national-security or homeland-security implications; (2) the importance of those implications; and (3) the degree to which the cited implications would be adversely affected in the absence of an exclusion. In that circumstance, in conducting a discretionary section 4(b)(2) exclusion analysis, we will give great weight to national-security and homeland-security concerns in analyzing the benefits of exclusion.

In preparing this proposal, we have determined that the lands within the proposed designation of critical habitat for Panama City crayfish are not owned,

managed, or used by the DoD or DHS, and, therefore, we anticipate no impact on national security or homeland security. However, during the development of a final designation, we will consider any additional information received through the public comment period on the impacts of the proposed designation on national security or homeland security to determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19.

Consideration of Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security discussed above. We consider a number of factors, including whether there are permitted conservation plans covering the species in the area such as HCPs, safe harbor agreements (SHAs), or candidate conservation agreements with assurances (CCAAs), or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at the existence of Tribal conservation plans and partnerships and consider the government-to-government relationship of the United States with Tribal entities. We also consider any social impacts that might occur because of the designation.

In preparing this proposal, we have determined that there are currently no HCPs or other management plans for the Panama City crayfish, and the proposed designation does not include any Tribal lands or trust resources. We anticipate no impact on Tribal lands, partnerships, or HCPs from this proposed critical habitat designation. Additionally, as described above, we are not considering excluding any particular areas from critical habitat on the basis of impacts to national security or economic impacts. However, during the development of a final designation, we will consider any additional information we receive through the public comment period regarding other relevant impacts of the proposed designation and will determine whether any specific areas should be excluded from the final critical habitat designation under authority of section 4(b)(2) and our implementing regulations at 50 CFR 424.19.

Required Determinations

Clarity of the Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(1) Be logically organized;

(2) Use the active voice to address readers directly;

(3) Use clear language rather than jargon;

(4) Be divided into short sections and sentences; and

(5) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the numbers of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; 5 U.S.C. 801 *et seq.*), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine if potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement

(avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, it is our position that only Federal action agencies would be directly regulated if we adopt the proposed critical habitat designation. There is no requirement under the RFA to evaluate the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities would be directly regulated by this rulemaking, the Service certifies that, if made final as proposed, the proposed critical habitat designation will not have a significant economic impact on a substantial number of small entities.

In summary, we have considered whether the proposed designation would result in a significant economic impact on a substantial number of small entities. For the above reasons and based on currently available information, we certify that, if made final, the proposed critical habitat designation would not have a significant economic impact on a substantial number of small business entities. Therefore, an initial regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use—Executive Order 13211

Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use) requires agencies to prepare Statements of Energy Effects when undertaking certain actions. In our economic analysis, we did not find that the designation of this proposed critical habitat would significantly affect energy supplies, distribution, or use because these were not identified as land use sectors within the critical habitat areas. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This proposed rule would not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandate'' includes a regulation that ''would impose an enforceable duty upon State, local, or tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions do not destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) We do not believe that this rule would significantly or uniquely affect small governments. Small governments will be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat. Therefore, a Small Government Agency Plan is not required.

Takings—Executive Order 12630

In accordance with E.O. 12630 (Government Actions and Interference with Constitutionally Protected Private Property Rights), we have analyzed the potential takings implications of designating critical habitat for the Panama City crayfish in a takings implications assessment. The Act does not authorize the Service to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed for the proposed designation of critical habitat for the Panama City crayfish, and it concludes that, if adopted, this designation of critical habitat does not pose significant takings implications for lands within or affected by the designation.

Federalism—Executive Order 13132

In accordance with E.O. 13132 (Federalism), this proposed rule does not have significant Federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this proposed critical habitat designation with, appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between the national government and the States, or on the distribution of powers and responsibilities among the various levels of government. The proposed designation may have some benefit to these governments because the areas

that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform—Executive Order 12988

In accordance with Executive Order 12988 (Civil Justice Reform), the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We have proposed designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this proposed rule identifies the elements of physical or biological features essential to the conservation of the species. The proposed areas of critical habitat are presented on maps, and the proposed rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

It is our position that, outside the jurisdiction of the U.S. Court of Appeals for the Tenth Circuit, we do not need to prepare environmental analyses pursuant to the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) in connection with regulations adopted pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This position was upheld by the U.S. Court of Appeals for the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied 516 U.S. 1042 (1996)).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes. We have determined that no Tribal lands fall within the boundaries of the proposed critical habitat for the Panama City crayfish, so no Tribal lands would be affected by the proposed designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *http://www.regulations.gov* and upon request from the Panama City Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rulemaking are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Florida Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. Amend § 17.46 by adding paragraph (d) to read as follows:

§ 17.46 Special rules—crustaceans.

* * * * *

(d) Panama City Crayfish (*Procambarus econfinae*)—(1) *Prohibitions.* The following prohibitions that apply to endangered wildlife also apply to the Panama City crayfish. Except as provided under paragraph (d)(2) of this section and §§ 17.4 and 17.5, it is unlawful for any person subject to the jurisdiction of the United States to commit, to attempt to commit, to solicit another to commit, or cause to be committed, any of the following acts in regard to these species:

(i) Import or export, as set forth at § 17.21(b) for endangered wildlife.

(ii) Take, as set forth at § 17.21(c)(1) for endangered wildlife.

(iii) Possession and other acts with unlawfully taken specimens, as set forth at § 17.21(d)(1) for endangered wildlife.

(iv) Interstate or foreign commerce in the course of a commercial activity, as set forth at § 17.21(e) for endangered wildlife.

(v) Sale or offer for sale, as set forth at § 17.21(f) for endangered wildlife.

(2) *Exceptions from prohibitions.* In regard to this species, you may:

(i) Conduct activities as authorized by a permit under § 17.32.

(ii) Take, as set forth at § 17.21(c)(2) through (c)(4) for endangered wildlife.

(iii) Take as set forth at § 17.31(b).

(iv) Take incidental to an otherwise lawful activity caused by:

(A) Conservation and restoration efforts by the Service or State wildlife agencies, including, but not limited to, collection of broodstock, tissue collection for genetic analysis, captive propagation, subsequent stocking into unoccupied areas within the historical range of the species and follow-up

monitoring, and actions necessary to aid a sick, injured, or orphaned specimen, to dispose of a dead specimen, or to salvage a dead specimen which may be useful for scientific study.

(B) Development practices that:

(*1*) Maintain existing structures and construction or reconstruction activities that occur within the existing footprint of previously developed areas;

(*2*) Build new structures that occur within 100 feet of existing structures on an individual private landowner's property and with a new footprint less than 1,000 square feet, such as a pool or shed associated with an existing house;

(*3*) Install culverts for individual landowners not associated with housing developments on lands greater than one acre;

(*4*) Build platforms or boardwalks for recreational purposes on conservation lands that allow sunlight of sufficient levels to maintain herbaceous groundcover;

(*5*) Build paths used for nonmotorized activities as long as the project footprint, including construction impacts, alter no more than 5 percent of the acreage in core or secondary soils within lands under a conservation easement.

(C) Certain land management activities, including:

(*1*) Silvicultural (forestry) activities located in secondary soils that follow state best management practices (BMPs);

(*2*) Prescribed burning and wildfire control efforts when following state BMPs, guidelines, or permit conditions;

(*3*) Herbicide application activities targeting exotic plants or shrub species when following all other state and federal BMPs, guidelines, or permit conditions;

(*4*) Agricultural maintenance activities in pasture and rangelands (including cattle operations) that were established prior to January 3, 2018, that do not have indirect impacts to adjacent Panama City crayfish habitat.

(D) Utility actions, including:

(*1*) Ditch mowing and maintenance outside of critical habitat units;

(*2*) Ditch mowing or maintenance within critical habitat units after coordination with the local FWS office;

(*3*) Culvert replacements or maintenance on individual landowner properties that do not adversely affect, but improve or restore, the natural hydrology;

(*4*) After coordination with the local FWS office the following: Maintenance associated with rights-of-way or powerlines, powerline and pole placements and replacements, and directional boring.

(v) Possess and engage in other acts with unlawfully taken wildlife, as set forth at § 17.21(d)(2) for endangered wildlife.

■ 3. Amend § 17.95(h) by adding an entry for ''Panama City Crayfish *(Procambarus econfinae*)'', in the same alphabetical order that it appears in the table at § 17.11(h), to read as follows:

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(h) * * *

Panama City Crayfish *(Procambarus econfinae*)

(1) Critical habitat units are depicted for Bay County, Florida, on the maps below.

(2) Within these areas, the physical or biological features essential to the conservation of Panama City crayfish consist of the following components:

(i) Undeveloped lands, including cropland, utilities rights-of-way, timberlands, and grazing lands, that support open wet pine flatwoods and wet prairie habitats that contain the following:

(A) Appropriate herbaceous groundcover vegetation;

(B) Permanent or temporary pools of shallow (usually less than 1 foot) freshwater locations; and

(C) Gently-sloped ground level swales with a 3:1 or shallower slope ratio along ecotonal areas.

(ii) Soil types within undeveloped lands that provide sediment structure needed for burrow construction and that support mostly native herbaceous vegetation needed for food and cover, and where the ground water is always within 3 feet of the ground surface and surface waters occur on occasion. These soil types include:

(A) Core soils for Panama City crayfish, including Pamlico-Dorovan Complex, Rutlege Sand, Plummer Sand, Pelham Sand, Pantego Sandy Loam, and Rutledge-Pamlico Complex;

(B) Secondary soils within 100 meters (328 feet) of core soils: Albany Sand, Leefield Sand, Leon Fine Sand, Osier Fine Sand, and Alapaha Loamy Sand; and

(C) Currently, or can eventually, support native herbaceous vegetation such as, but not limited to, wiregrass (*Aristida beyrichiana*), redroot (*Lachnanthes caroliniana*), beakrushes (*Rhynchospora* spp.), pitcher plants (*Sarracenia* spp.), sundews (*Drosera* spp.), butterworts (*Pinguicula* spp.), and lilies (*Hymenocallis* spp.).

(iii) Undeveloped lands that contain surface and groundwater of sufficient quality to support all life stages of the Panama City crayfish and the herbaceous vegetation on which they rely, specifically surface waters with:

(A) Oxygen levels that range between 2 and 9 milligrams per liter;

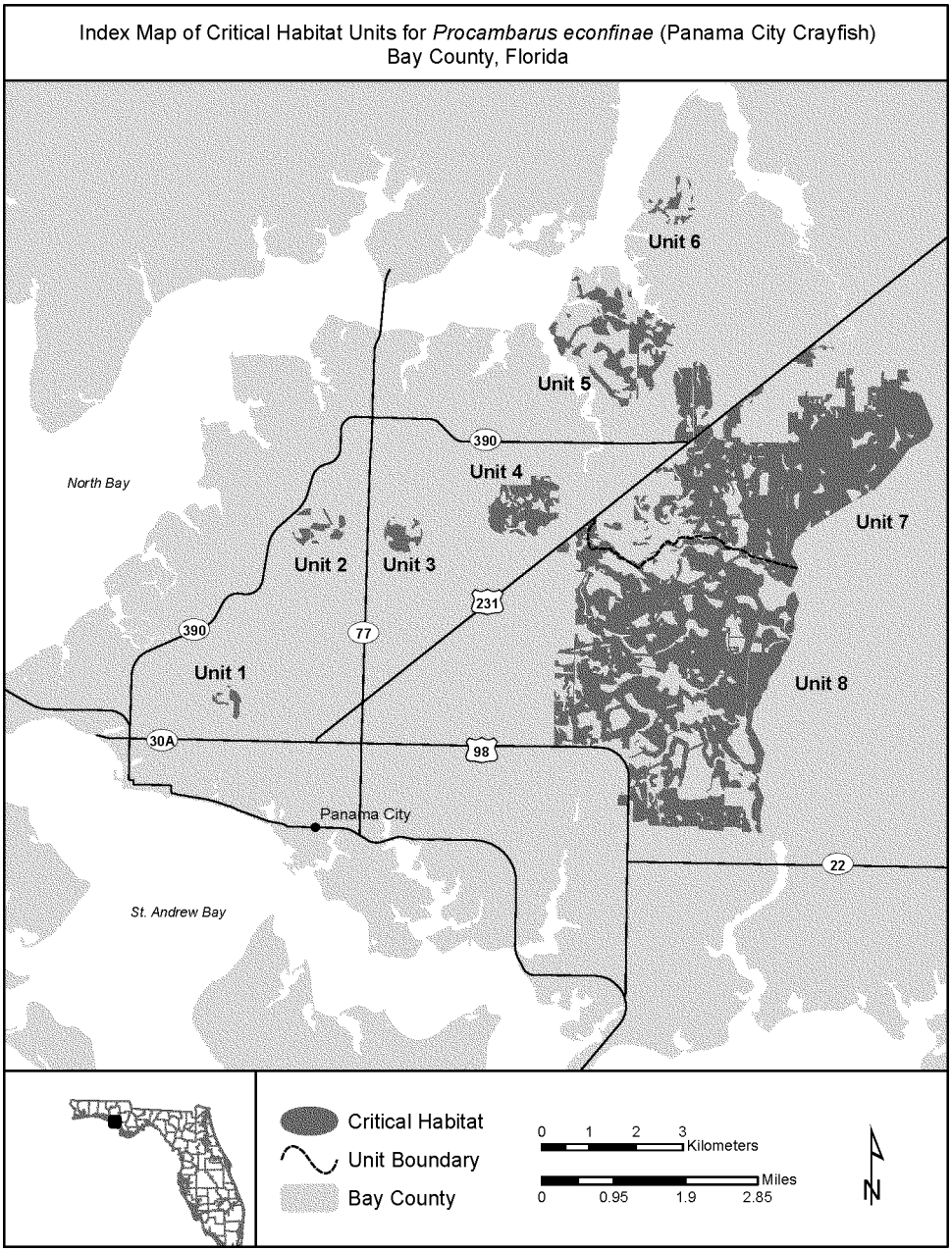
(B) pH levels between 4.1 and 9.2; and

(C) temperatures between 42 and 94 degrees Fahrenheit (°F) (5 and 34.4 degrees Celsius (°C)), although optimum temperatures are thought to be in the range of 68 to 79 °F (20 to 26 °C).

(3) Critical habitat does not include manmade structures (such as buildings, aqueducts, runways, roads, and other paved areas) and the land on which they are located existing within the legal boundaries on the effective date of the final rule.

(4) *Critical habitat map units.* Data layers defining map units were created based on known occurrences and habitat requirements. Critical habitat units were mapped in ArcMap (ESRI, Inc.) using the U.S. Department of Agriculture, Natural Resources Conservation Service, Soil Survey Geographic Database dataset. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The shapefiles on which each map is based are available to the public at *http://www.regulations.gov* at Docket No. FWS–R4–ES–2020–0137 and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

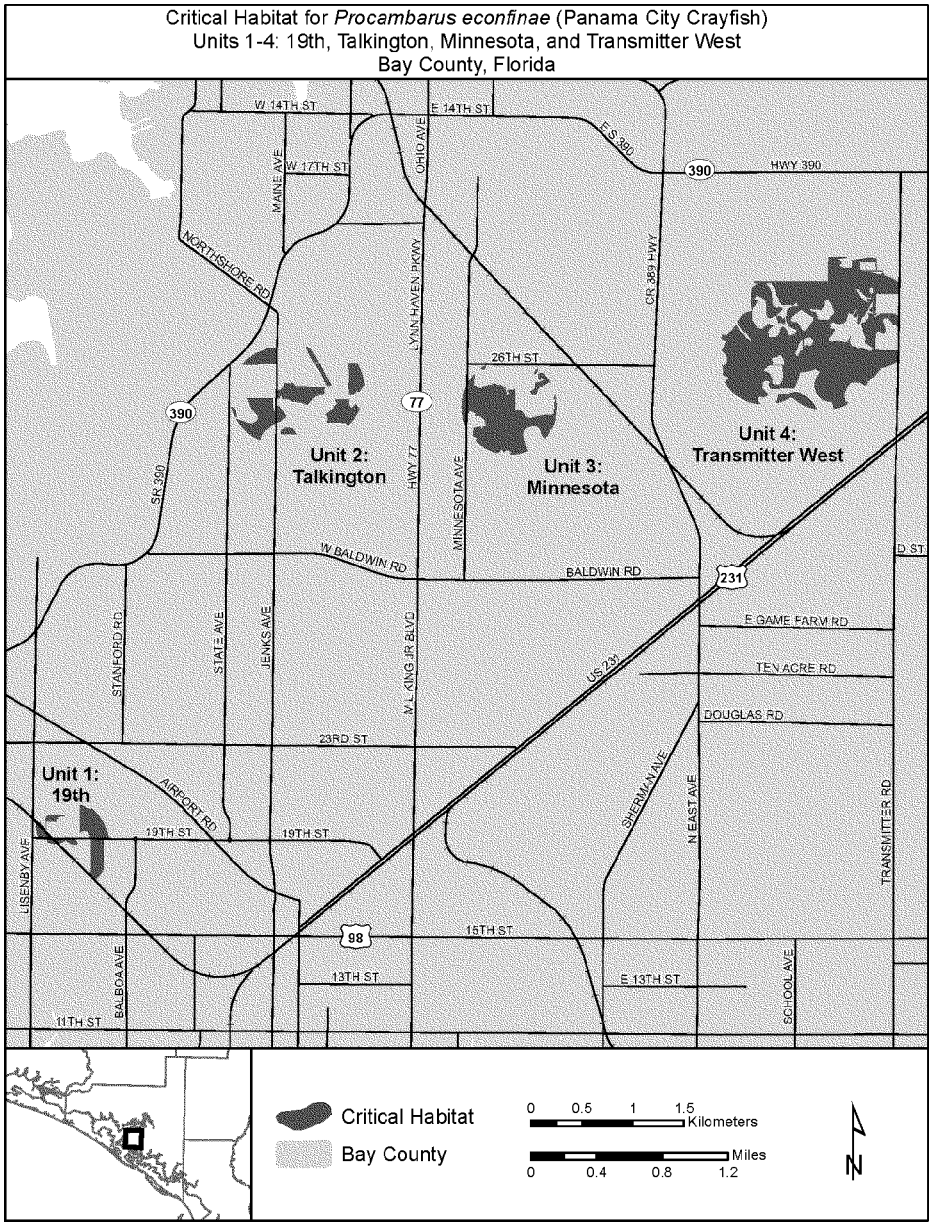
(5) *Note:* Index map follows:



(6) Unit 1: 19th Street, Bay County, Florida.

(i) *General description:* Unit 1 consists of 24.3 acres (9.8 hectares) and is composed of lands in State, county, or city ownership (3.7 ac (1.5 ha)), and private ownership (20.6 ac (8.3 ha)).

(ii) Map of Units 1, 2, 3, and 4 follows:



(7) Unit 2: Talkington, Bay County, Florida.

(i) *General description:* Unit 2 consists of 53.1 acres (21.5 hectares) and is composed of lands entirely in private ownership.

(ii) Map of Unit 2 is provided at paragraph (6)(ii) of this entry.

(8) Unit 3: Minnesota, Bay County, Florida.

(i) *General description:* Unit 3 consists of 65.0 acres (26.3 hectares) and is composed of lands in State, county, or city ownership (37.2 ac (15.0 ha)), and private ownership (27.9 ac (11.3 ha)).

(ii) Map of Unit 3 is provided at paragraph (6)(ii) of this entry.

(9) Unit 4: Transmitter West, Bay County, Florida.

(i) *General description:* Unit 4 consists of 248.4 acres (100.5 hectares) and is composed of lands in State, county, or city ownership (4.7 ac (1.9 ha)), and private ownership (243.7 ac (98.6 ha)).

(ii) Map of Unit 4 is provided at paragraph (6)(ii) of this entry.

(10) Unit 5: Deer Point, Bay County, Florida.

(i) *General description:* Unit 5 consists of 414.6 ac (167.8 ha) and is composed of lands in State, county, or city ownership (0.9 ac (0.4 ha)), and private ownership (413.8 ac (167.5 ha)).

(ii) Map of Units 5 and 6 follows:

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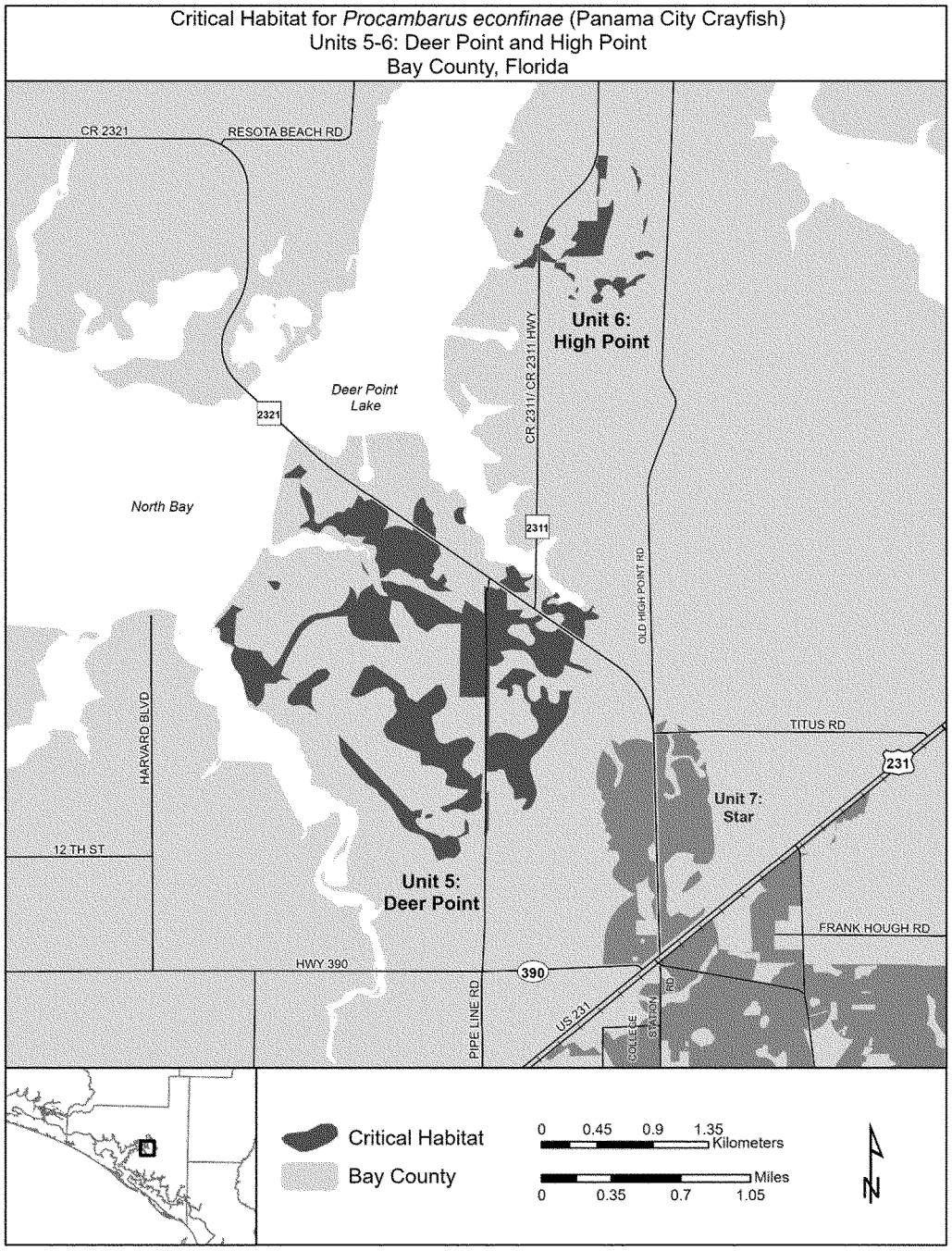


(11) Unit 6: High Point, Bay County, Florida.

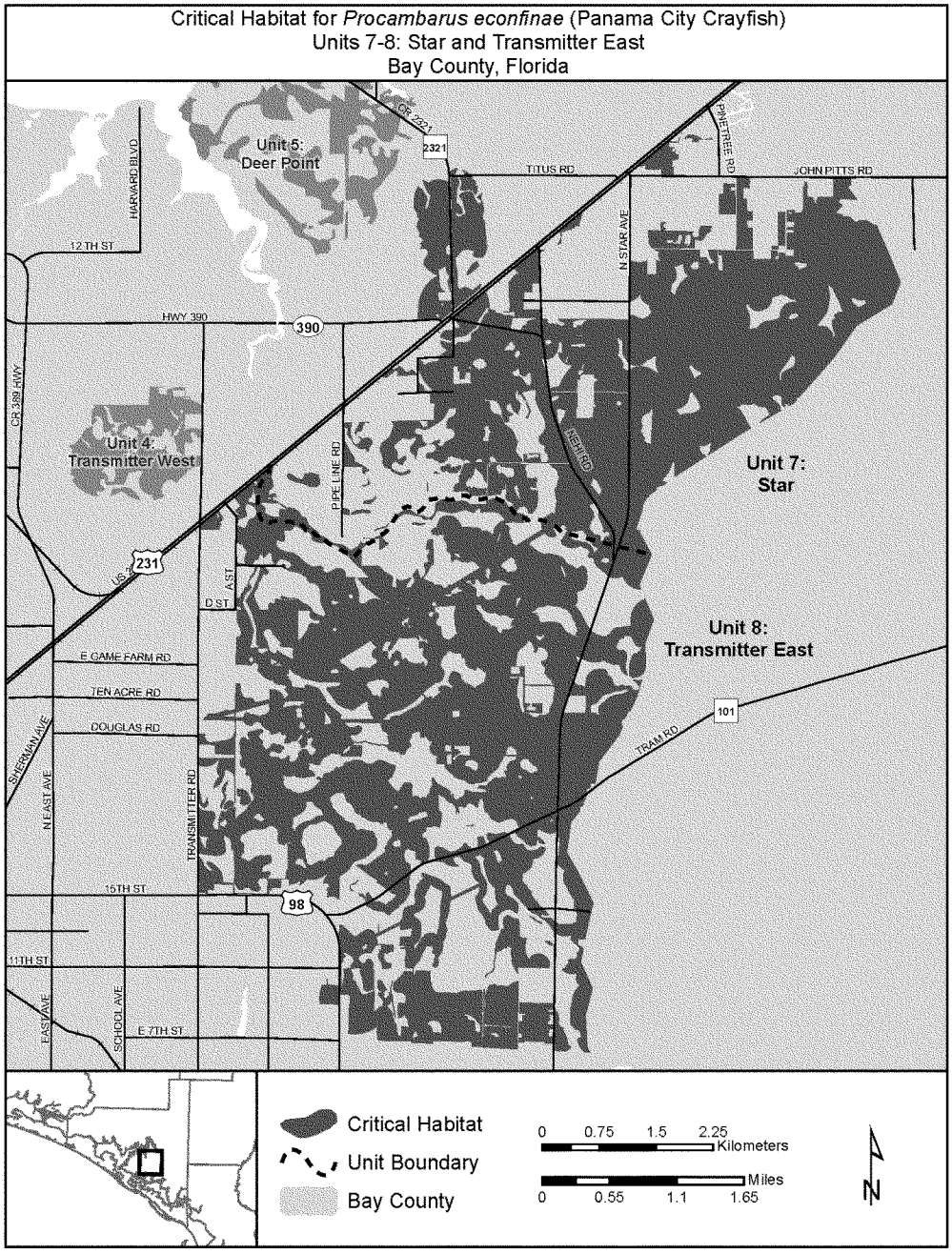
(i) *General description:* Unit 6 consists of 38.4 ac (15.5 ha) and is composed of lands in State, county, or city ownership (0.5 ac (0.2 ha)), and private ownership (37.9 ac (15.3 ha)).

(ii) Map of Unit 6 is provided at paragraph (10)(ii) of this entry.

(12) Unit 7: Star, Bay County, Florida.

(i) *General description:* Unit 7 consists of 2,761.4 ac (1,117.5 ha) and is composed of lands in State, county, or city ownership (9.7 ac (4.0 ha)), and private ownership (2,751.6 ac (1,113.5 ha)).

(ii) Map of Units 7 and 8 follows:



(13) Unit 8: Transmitter East, Bay County, Florida.

(i) *General description:* Unit 8 consists of 3,571.5 ac (1,445.4 ha) and is composed of lands in State, county, or city ownership (82.5 ac (33.4 ha)), and private ownership (3,489.0 ac (1,412.0 ha)).

(ii) Map of Unit 8 is provided at paragraph (12)(ii) of this entry.

* * * * *

Martha Williams,

Principal Deputy Director, Exercising the Delegated Authority of the Director, U.S. Fish and Wildlife Service.

[FR Doc. 2021–07243 Filed 4–14–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 223 and 224

[Docket No. 210409–0078;RTID 0648–XR116]

Endangered and Threatened Wildlife; 90-Day Finding on a Petition To List the Shortfin Mako Shark as Threatened or Endangered Under the Endangered Species Act

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: 90-day petition finding, request for information, and initiation of status review.

SUMMARY: We, NMFS, announce a 90-day finding on a petition to list the shortfin mako shark (*Isurus oxyrinchus*) as threatened or endangered under the Endangered Species Act (ESA) and to designate critical habitat concurrent with the listing. We find that the petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted. Therefore, we are initiating a status review of the species to determine whether listing under the ESA is warranted. To ensure this status review is comprehensive, we are soliciting scientific and commercial information regarding this species.

DATES: Scientific and commercial information pertinent to the petitioned action must be received by June 14, 2021.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2021–0028 by the following method:

• *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *https://www.regulations.gov* and enter NOAA–NMFS–2021–0028 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Interested persons may obtain a copy of the petition online at the NMFS website: *https://www.fisheries.noaa.gov/national/endangered-species-conservation/petitions-awaiting-90-day-findings.*

FOR FURTHER INFORMATION CONTACT: Adrienne Lohe, NMFS Office of Protected Resources, (301) 427–8442, *Adrienne.Lohe@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

On January 25, 2021, we received a petition from Defenders of Wildlife to list the shortfin mako shark (*Isurus oxyrinchus*) as a threatened or endangered species under the ESA and to designate critical habitat concurrent with the listing. The petition asserts that *I. oxyrinchus* is threatened by 4 of the 5 ESA section 4(a)(1) factors: (1) Present and threatened modification of its habitat; (2) overutilization for commercial and recreational purposes; (3) inadequacy of existing regulatory mechanisms; and (4) other natural or manmade factors. The petition is available online (see **ADDRESSES**).

ESA Statutory, Regulatory, and Policy Provisions and Evaluation Framework

Section 4(b)(3)(A) of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), requires, to the maximum extent practicable, that within 90 days of receipt of a petition to list a species as threatened or endangered, the Secretary of Commerce make a finding on whether that petition presents substantial scientific or commercial information indicating that the petitioned action may be warranted, and to promptly publish such finding in the **Federal Register** (16 U.S.C. 1533(b)(3)(A)). When it is found that substantial scientific or commercial information in a petition indicates the petitioned action may be warranted (a ''positive 90-day finding''), we are required to promptly commence a review of the status of the species concerned during which we will conduct a comprehensive review of the best available scientific and commercial information. In such cases, we conclude the review with a finding as to whether, in fact, the petitioned action is warranted within 12 months of receipt of the petition. Because the finding at the 12-month stage is based on a more thorough review of the available information, as compared to the narrow scope of review at the 90-day stage, a ''may be warranted'' finding does not prejudge the outcome of the status review.

Under the ESA, a listing determination may address a species, which is defined to also include subspecies and, for any vertebrate species, any distinct population segment (DPS) that interbreeds when mature (16 U.S.C. 1532(16)). A joint NMFS–U.S. Fish and Wildlife Service (USFWS) (jointly, ''the Services'') policy clarifies the agencies' interpretation of the phrase ''distinct population segment'' for the purposes of listing, delisting, and reclassifying a species under the ESA (61 FR 4722; February 7, 1996). A species, subspecies, or DPS is ''endangered'' if it is in danger of extinction throughout all or a significant portion of its range, and ''threatened'' if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range (ESA sections 3(6) and 3(20), respectively, 16 U.S.C. 1532(6) and (20)). Pursuant to the ESA and our implementing regulations, we determine whether species are threatened or endangered based on any one or a combination of the following five section 4(a)(1) factors: (1) The present or threatened destruction, modification, or curtailment of habitat or range; (2) overutilization for commercial, recreational, scientific, or educational purposes; (3) disease or predation; (4) inadequacy of existing regulatory mechanisms to address identified threats; (5) or any other natural or manmade factors affecting the species' existence (16 U.S.C. 1533(a)(1), 50 CFR 424.11(c)).

ESA-implementing regulations issued jointly by NMFS and USFWS (50 CFR 424.14(h)(1)(i)) define ''substantial scientific or commercial information'' in the context of reviewing a petition to list, delist, or reclassify a species as credible scientific or commercial information in support of the petition's claims such that a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted. Conclusions drawn in the petition without the support of credible scientific or commercial information will not be considered ''substantial information.'' In reaching the initial (90-day) finding on the petition, we will consider the information described in sections 50 CFR 424.14(c), (d), and (g) (if applicable).

Our determination as to whether the petition provides substantial scientific or commercial information indicating that the petitioned action may be warranted will depend in part on the degree to which the petition includes the following types of information: (1) Information on current population status and trends and estimates of current population sizes and distributions, both in captivity and the wild, if available; (2) identification of the factors under section 4(a)(1) of the ESA that may affect the species and where these factors are acting upon the species; (3) whether and to what extent any or all of the factors alone or in combination identified in section 4(a)(1) of the ESA may cause the species to be an endangered species or threatened species (*i.e.,* the species is currently in danger of extinction or is likely to become so within the foreseeable

future), and, if so, how high in magnitude and how imminent the threats to the species and its habitat are; (4) information on adequacy of regulatory protections and effectiveness of conservation activities by States as well as other parties, that have been initiated or that are ongoing, that may protect the species or its habitat; and (5) a complete, balanced representation of the relevant facts, including information that may contradict claims in the petition. See 50 CFR 424.14(d).

If the petitioner provides supplemental information before the initial finding is made and states that it is part of the petition, the new information, along with the previously submitted information, is treated as a new petition that supersedes the original petition, and the statutory timeframes will begin when such supplemental information is received. See 50 CFR 424.14(g).

We may also consider information readily available at the time the determination is made. We are not required to consider any supporting materials cited by the petitioner if the petitioner does not provide electronic or hard copies, to the extent permitted by U.S. copyright law, or appropriate excerpts or quotations from those materials (*e.g.,* publications, maps, reports, letters from authorities). See 50 CFR 424.14(c)(6).

The ''substantial scientific or commercial information'' standard must be applied in light of any prior reviews or findings we have made on the listing status of the species that is the subject of the petition. Where we have already conducted a finding on, or review of, the listing status of that species (whether in response to a petition or on our own initiative), we will evaluate any petition received thereafter seeking to list, delist, or reclassify that species to determine whether a reasonable person conducting an impartial scientific review would conclude that the action proposed in the petition may be warranted despite the previous review or finding. Where the prior review resulted in a final agency action—such as a final listing determination, 90-day not-substantial finding, or 12-month not-warranted finding—a petition will generally not be considered to present substantial scientific and commercial information indicating that the petitioned action may be warranted unless the petition provides new information or analysis not previously considered. See 50 CFR 424.14(h)(1)(iii).

At the 90-day finding stage, we do not conduct additional research, and we do not solicit information from parties outside the agency to help us in evaluating the petition. We will accept the petitioners' sources and characterizations of the information presented if they appear to be based on accepted scientific principles, unless we have specific information in our files that indicates the petition's information is incorrect, unreliable, obsolete, or otherwise irrelevant to the requested action. Information that is susceptible to more than one interpretation or that is contradicted by other available information will not be dismissed at the 90-day finding stage, so long as it is reliable and a reasonable person conducting an impartial scientific review would conclude it supports the petitioners' assertions. In other words, conclusive information indicating the species may meet the ESA's requirements for listing is not required to make a positive 90-day finding. We will not conclude that a lack of specific information alone necessitates a negative 90-day finding if a reasonable person conducting an impartial scientific review would conclude that the unknown information itself suggests the species may be at risk of extinction presently or within the foreseeable future.

To make a 90-day finding on a petition to list a species, we first evaluate whether the information presented in the petition, in light of the information readily available in our files, indicates that the petitioned entity constitutes a ''species'' eligible for listing under the ESA. Next, if we conclude the petition presents substantial scientific or commercial information suggesting that the petitioned entity may constitute a ''species,'' we evaluate whether the information indicates that the species may face an extinction risk such that listing, delisting, or reclassification may be warranted; this may be indicated in information expressly discussing the species' status and trends, or in information describing impacts and threats to the species. We evaluate whether the petition presents any information on specific demographic factors pertinent to evaluating extinction risk for the species (*e.g.,* population abundance and trends, productivity, spatial structure, age structure, sex ratio, diversity, current and historical range, habitat integrity or fragmentation), and the potential contribution of identified demographic risks to extinction risk for the species. We then evaluate whether the petition presents information suggesting potential links between these demographic risks and the causative impacts and threats identified in section 4(a)(1) of the ESA.

Information presented on impacts or threats should be specific to the species and should reasonably suggest that one or more of these factors may be operative threats that act or have acted on the species to the point that it may warrant protection under the ESA. Broad statements about generalized threats to the species, or identification of factors that could negatively impact a species, do not constitute substantial information indicating that listing may be warranted. We look for information indicating that not only is the particular species exposed to a factor, but that the species may be responding in a negative fashion; then we assess the potential significance of that negative response.

Many petitions identify risk classifications made by nongovernmental organizations, such as the International Union on the Conservation of Nature (IUCN), the American Fisheries Society, or NatureServe, as evidence of extinction risk for a species. Risk classifications by other organizations or made under other Federal or state statutes may be informative, but such classification alone may not provide the rationale for a positive 90-day finding under the ESA. For example, as explained by NatureServe, their assessments of a species' conservation status do ''not constitute a recommendation by NatureServe for listing under the U.S. Endangered Species Act'' because NatureServe assessments ''have different criteria, evidence requirements, purposes and taxonomic coverage than government lists of endangered and threatened species, and therefore these two types of lists should not be expected to coincide'' (*https://explorer.natureserve.org/AboutTheData/DataTypes/ConservationStatusCategories*). Additionally, species classifications under IUCN and the ESA are not equivalent; data standards, criteria used to evaluate species, and treatment of uncertainty are also not necessarily the same. Thus, when a petition cites such classifications, we will evaluate the source of information that the classification is based upon in light of the standards on extinction risk and impacts or threats discussed above.

Distribution, Habitat, and Life History

The shortfin mako is a large pelagic shark that occurs across all temperate and tropical ocean waters (Rigby *et al.* 2019; Santos *et al.* 2020). The species is highly migratory and is known to travel long distances in open ocean, continental shelf, shelf edge, and shelf

slope habitats (Rogers *et al.* 2015). The species also displays fidelity to small geographic areas on or near continental shelves and coastal areas of high productivity, although this resident behavior is rarely observed in the open ocean (Rogers *et al.* 2015; Francis *et al.* 2019). Shortfin mako shark vertical distribution in the water column is affected by water temperature, dissolved oxygen (DO) concentration, and time of day. The preferred water temperature of the species is thought to range between 17 °C and 22 °C (Casey and Kohler 1992; Nasby-Lucas *et al.* 2019; Santos *et al.* 2020), though the species also regularly occupies waters between 22 °C and 31 °C (Vaudo *et al.* 2017). As the species has one of the highest measured metabolic rates of any shark, it typically inhabits waters with DO concentrations of at least 3 milliliters per liter and avoids areas with low levels of DO (Sepulveda *et al.* 2007; Abascal *et al.* 2011). Individuals spend most of their time in the upper part of the water column but dive to depths of several hundred meters, allowing them to forage for mesopelagic fishes and squid, though dives may have other functions including navigation (Francis *et al.* 2019). Tagging studies have found that the species typically spends more time in deeper, colder water during the daytime and at night moves to shallower, warmer waters (Sepulveda *et al.* 2004; Loefer *et al.* 2005; Stevens *et al.* 2010; Abascal *et al.* 2011; Nasby-Lucas *et al.* 2019). Although thermal barriers have consistently been shown to limit shortfin mako movement between different regions (Casey and Kohler 1992; Vaudo *et al.* 2017; Corrigan *et al.* 2018; Santos *et al.* 2020), genetic studies indicate a globally panmictic population with some genetic structuring between ocean basins (Schrey and Heist 2003; Corrigan *et al.* 2018).

Shortfin makos are estimated to live to at least 29 years, and males and females reach maturity at approximately 7–8 years and 18–19 years, respectively (Bishop *et al.* 2006; Natanson *et al.* 2006). Natural mortality levels for the species are low (Bishop *et al.* 2006). Females have a 3-year reproductive cycle (Mollet *et al.* 2000), and estimates of gestation time vary from 9 months to 25 months (Mollet *et al.* 2000; Duffy and Francis 2001; Joung and Hsu 2005; Semba *et al.* 2011). Litter size typically ranges from 4 to 25 pups (Mollet *et al.* 2000; Joung and Hsu 2005). As the species is late maturing and slow growing with moderately high longevity and low annual fecundity, its productivity is very low (Bishop *et al.* 2006).

Status and Population Trends

While there are no data available on the global abundance of shortfin mako sharks, stock assessments and standardized catch-per-unit-effort (CPUE) data indicate that the species is declining globally (CITES 2019; Rigby *et al.* 2019). Overall, the species has experienced an estimated median population reduction of 46.6 percent, with the highest probability of 50–79 percent reduction over three generation lengths (72–75 years) (Rigby *et al.* 2019). All regional populations are in decline with the exception of the South Pacific, which shows some evidence of population increases (Rigby *et al.* 2019).

The steepest population declines are indicated in the North and South Atlantic (Rigby *et al.* 2019). The most recent stock assessment by the International Commission for the Conservation of Atlantic Tunas (ICCAT) indicates a 90 percent probability that the North Atlantic stock is in an overfished state and is experiencing overfishing (ICCAT 2019b). Trend analysis of modeled biomass in the North Atlantic estimates a median decline of 60 percent between 1950 and 2017 (Rigby *et al.* 2019). Although ICCAT reports a high degree of uncertainty in the status of the South Atlantic stock (ICCAT 2019b), standardized catch rates in South Atlantic longlines indicate steep declines of 99 percent in the average CPUE of 1979–1997 and 1998–2007 (Rigby *et al.* 2019 citing Barreto *et al.* 2016). Further, long-term combined trends for shortfin mako and porbeagle (*Lamna nasus*) in the Mediterranean Sea indicate a 99.99 percent decrease in abundance and biomass since the early 19th century (Ferretti *et al.* 2008).

Declines in the Indian and North Pacific Oceans are also evident, but not as steep as those indicated in the Atlantic (Rigby *et al.* 2019). Although the International Scientific Committee for Tuna and Tuna-like Species in the North Pacific Ocean (ISC) Shark Working Group (2018) found that the North Pacific stock was likely not in an overfished condition and was likely not experiencing overfishing between 1975 and 2016 (42 years), the IUCN Red List assessment of the trend over three generations (72 years) indicated a median decline of 36.5 percent (Rigby *et al.* 2019). Additionally, data from the Western and Central Pacific Fisheries Commission (WCPFC) indicate that longline catch rates of mako sharks (shortfin and longfin mako (*Isurus paucus*) combined) in the North Pacific declined significantly by an average of 7 percent (90 percent confidence interval: 3 to 11 percent) annually between 1995 and 2010 (Clarke *et al.* 2013). A preliminary stock assessment in the Indian Ocean indicates that the stock is experiencing overfishing, but is not yet overfished (Brunel *et al.* 2018). The trend analysis for modeled biomass in the Indian Ocean indicates a median decline of 47.9 percent over three generation lengths (Rigby *et al.* 2019).

In the South Pacific, trend analysis of modeled biomass indicates a median increase of 35.2 percent over three generation lengths (Rigby *et al.* 2019). Longline catch rates reported to WCPFC did not indicate a significant trend in abundance of mako (shortfin and longfin combined) in the South Pacific between 1995 and 2010 (Clarke *et al.* 2013).

In sum, while data on abundance and trends are incomplete, the information presented in the petition indicates that the species is declining across its range, with the exception of the South Pacific.

Analysis of ESA Section 4(a)(1) Factors

The petition asserts that *I. oxyrinchus* is threatened by four of the five ESA section 4(a)(1) factors: Present and threatened modification of its habitat, overutilization for commercial and recreational purposes, inadequacy of existing regulatory mechanisms, and other natural or manmade factors, including climate change. Information in the petition and readily available in our files indicates that the primary threat facing the species is overutilization in fisheries worldwide, and we find that listing the shortfin mako as a threatened or endangered species under the ESA may be warranted based on this threat alone. As such, we focus our discussion below on the evidence of overutilization in commercial fisheries. However, we note that in the status review for this species, we will evaluate all ESA section 4(a)(1) factors to determine whether any one or a combination of these factors are causing declines in the species or are likely to substantially negatively affect the species within the foreseeable future to such a point that the shortfin mako is at risk of extinction or likely to become so in the foreseeable future.

Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

According to information cited in the petition and readily available in our files, the greatest threat to the shortfin mako shark is historical and ongoing overfishing. Shortfin mako sharks are targeted in semi-industrial and artisanal

fisheries in the Indian Ocean and as sportfish in recreational fisheries, though the majority of the catch is taken incidentally in commercial fisheries targeting tuna, billfish, and swordfish throughout the species' range (Camhi *et al.* 2008). According to the Food and Agriculture Organization of the United Nations (FAO) global capture production statistics, total reported catch for the shortfin mako in the period 2010–2016 totaled 91,989 metric tons (t) (CITES 2019). Landings in the Atlantic totaled 45,959 t (50 percent of global reported catch), in the Pacific totaled 31,838 t (34 percent of global reported catch), in the Indian Ocean totaled 14,043 t (15 percent of global reported catch), and in the Mediterranean totaled 152 t (less than 1 percent of global reported catch) (CITES 2019). Reported catch, however, is a substantial underestimate of actual catch. Campana (2016) estimates that in the Atlantic, only 25 percent of the total catch is reported to ICCAT. Reported catch also does not account for mortalities that result from fisheries interactions, including sharks that are discarded, finned, or that experience post-release mortality. In fact, levels of fishing mortality in the Northwest Atlantic estimated through fisheries-independent satellite telemetry data were found to be 10 times greater than previous estimates from fisheries-dependent data, and 5–18 times greater than those associated with maximum sustainable yield (Byrne *et al.* 2017). Therefore, impacts of commercial fishing fleets on the shortfin mako are likely much greater than reported catch numbers suggest.

Shortfin makos are most commonly caught as bycatch in longline fisheries, and are also caught in gillnets, purse seines, trammel nets, and trawls (CITES 2019). When bycaught, the species experiences mortality through at-vessel or hooking mortality, and post-release mortality. Rates of at-vessel mortality, or mortality resulting from interactions with fishing gear prior to being brought onboard, have been estimated at 26.2 percent for shortfin makos bycaught in Northwest Atlantic pelagic longlines, though this varies by target species and fishing vessel (Campana *et al.* 2016). The proportion of shortfin makos that experience at-vessel mortality was significantly higher than that of blue sharks, likely because shortfin makos are obligate ram ventilators (*i.e.,* they must be continuously swimming forwards to move water over the gills) with high oxygen requirements, and their ability to ram ventilate is compromised once hooked (Campana 2016; Campana *et al.* 2016). The rate of post-release mortality has been estimated at 31.3 percent for shortfin makos bycaught by Northwest Atlantic pelagic longlines (Campana *et al.* 2016). Combining at-vessel and post-release mortality, total bycatch mortality in the Canadian pelagic longline fishery is estimated at 49.3 percent (95 percent confidence interval: 23–73 percent), assuming that no live sharks are retained (Campana *et al.* 2016). Other available estimates of post-release mortality for the species include 47 percent in the Hawaiian deep-set commercial longline fishery and 31.6 percent in the Hawaiian shallow-set commercial longline fishery (Walsh *et al.* 2009). In sum, shortfin makos experience substantial mortality as a result of being incidentally caught in commercial fisheries.

Shortfin makos also experience mortality through opportunistic retention, and are more frequently retained than other pelagic sharks based on their highly valued meat and fins (CITES 2019). The species is preferred in the Hong Kong fin market, one of the largest fin trading markets in the world (Fields *et al.* 2018). Clarke *et al.* (2006a) estimate that the species makes up approximately 2.7 percent (95 percent probability interval: 2.3 to 3.1 percent) of the Hong Kong shark fin trade, the fourth highest proportion of auctioned fin weight after blue (*Prionace glauca,* 17.3 percent), hammerhead (*Sphyrna zygaena* or *S. lewini,* 4.4 percent) and silky (*Carcharhinus falciformis,* 3.5 percent) sharks. A more recent study found shortfin makos to be the fifth most commonly traded species in Hong Kong based on random samples of fin trimmings from retail markets (Fields *et al.* 2018). The estimated number of shortfin makos utilized in the worldwide shark fin trade each year is between 300,000 and 1,000,000, totaling between 20,000 and 55,000 t in biomass (Clarke *et al.* 2006b). Beyond the fin trade, shortfin mako sharks are highly valued for their meat, which is utilized fresh, frozen, smoked, dried, and salted for human consumption (CITES 2019; Dent and Clarke 2015). Shortfin mako liver oil, teeth, jaws, and skin are also traded, though most of these products are of lower value and are not traded in significant quantities (CITES 2019).

The shortfin mako's low productivity and high susceptibility to capture give it one of the highest risks of overexploitation of sharks caught by Atlantic pelagic longline fleets (Cortés *et al.* 2015). Additionally, fisheries mortality primarily affects sub-adults (approximate ages of 3–15 years), meaning that as this exploited age-class matures, the reproductive population will shrink (Winker *et al.* 2020). For this reason, ICCAT (2019a) projects that even with zero total allowable catch in the North Atlantic, the stock would continue to decline until 2035, and would have only a 53 percent probability of being rebuilt and no longer subject to overfishing by 2045. Overall, the shortfin mako's recent population declines, low productivity, high vulnerability to overexploitation, and the long lag time between implementation of management measures (*e.g.,* reducing or eliminating allowable catch) and the start of population recovery lead us to conclude that listing the species as threatened or endangered may be warranted.

Petition Finding

After reviewing the petition, the literature cited in the petition, and other information readily available in our files, we find that listing *I. oxyrinchus* as a threatened or endangered species may be warranted. Therefore, in accordance with section 4(b)(3)(A) of the ESA and NMFS' implementing regulations (50 CFR 424.14(h)(2)), we will commence a status review of this species. During the status review, we will determine whether *I. oxyrinchus* is in danger of extinction (endangered) or likely to become so (threatened) throughout all or a significant portion of its range. As required by section 4(b)(3)(B) of the ESA, within 12 months of the receipt of the petition (January 25, 2021), we will make a finding as to whether listing the shortfin mako shark as an endangered or threatened species is warranted. If listing is warranted, we will publish a proposed rule and solicit public comments before developing and publishing a final rule.

Information Solicited

To ensure that the status review is based on the best available scientific and commercial data, we are soliciting comments and information from interested parties on the status of the shortfin mako shark. Specifically, we are soliciting information in the following areas:

(1) Historical and current abundance and population trends of *I. oxyrinchus* throughout its range;

(2) Historical and current distribution and population structure of *I. oxyrinchus;*

(3) Historical and current condition of habitat for *I. oxyrinchus;*

(3) Historical and current data on bycatch and retention of *I. oxyrinchus* in industrial, commercial, artisanal, and recreational fisheries worldwide;

(4) Data on trade of shortfin mako products, including fins, meat, jaws, skin, and liver oil; and

(5) The effects of other known or potential threats to *I. oxyrinchus* over the short-term or long-term; and

(5) Management, regulatory, or conservation programs for *I. oxyrinchus,* including mitigation measures related to any known or potential threats to the species throughout its range.

We request that all data and information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications. Please send any comments in accordance with the instructions provided in the **ADDRESSES** section above. We will base our findings on a review of the best available scientific and commercial information available, including all information received during the public comment period.

References Cited

A complete list of all references cited herein is available upon request (See **FOR FURTHER INFORMATION CONTACT**).

Authority: The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Dated: April 12, 2021.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2021–07714 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register
Vol. 86, No. 71
Thursday, April 15, 2021

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

AFRICAN DEVELOPMENT FOUNDATION

Public Quarterly Meeting of the Board of Directors

AGENCY: United States African Development Foundation.

ACTION: Notice of meeting.

SUMMARY: The US African Development Foundation (USADF) will hold its quarterly meeting of the Board of Directors to discuss the agency's programs and administration. This meeting will occur at the USADF office.

DATES: The meeting date is Tuesday, April 27, 2021, 10:00 a.m. to 11:30 a.m.

ADDRESSES: The meeting will be held by teleconference. Please contact the Agency Contact listed below for conference details.

FOR FURTHER INFORMATION CONTACT: Nina-Belle Mbayu, (202) 233–8808, *nbmbayu@usadf.gov*.

(Authority: Public Law 96–533 (22 U.S.C. 290h)).

Dated: April 12, 2021.

Nina-Belle Mbayu,

Acting General Counsel.

[FR Doc. 2021–07734 Filed 4–14–21; 8:45 am]

BILLING CODE 6117–01–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 966

[Doc. No. AMS–SC–20–0004; SC20–966–1]

Tomatoes Grown in Florida; Modification of Handling Requirements; Withdrawal

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule, withdrawal.

SUMMARY: The U.S. Department of Agriculture withdraws a proposed rule recommended by the Florida Tomato Committee (Committee) to revise the exemption, container, and definition sections under the Marketing Order's handling requirements and to update language to reflect current industry practices. After reviewing and considering the comments received, the proposed rule is being withdrawn.

DATES: As of April 15, 2021, the proposed rule published on June 9, 2020, at 85 FR 35222, is withdrawn.

FOR FURTHER INFORMATION CONTACT: Steven W. Kauffman, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Steven.Kauffman@usda.gov* or *Christian.Nissen@usda.gov.*

SUPPLEMENTARY INFORMATION: This withdrawal is issued under Marketing Agreement No. 125 and Order No. 966, as amended (7 CFR part 966), regulating the handling of tomatoes grown in Florida. Part 966 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers operating within the production area.

This action withdraws a proposed rule published in the **Federal Register** on June 9, 2020, (85 FR 35222) to revise the exemption, container, and definition sections in the handling requirements of the Order. Specifically, the proposal would have removed the exemption for pear shaped or Roma type tomatoes. This would have required Roma type tomatoes to meet the grade, pack and container, inspection, and reporting requirements, and Roma type tomatoes would have been subject to assessment under the Order.

The proposal also would have changed the exemption language for greenhouse and hydroponic tomatoes by eliminating the exemptions for greenhouse and hydroponic production and would have established a new exemption and definition for controlled environment production. It would have also adjusted the pack and container requirements, and updated language to reflect current industry practices.

During the proposed rule's 30-day comment period, eight comments were received. All the comments may be viewed on the internet at *http://www.regulations.gov.* Of the comments received, one comment favored aspects of the rule, and another favored implementing the handling requirements for Roma tomatoes, but opposed the new exemption definition for ''controlled environment.'' Four comments opposed removing the exemption for Roma tomatoes, and three of these comments also opposed the exemption change and definition for ''controlled environment'', with one further opposing the changes to the container requirements. The other comments received pertained to issues that were not applicable to the proposed rule.

The proposed rule would have established changes to the handling requirements of the tomato Order. However, section 8e of the Act (7 U.S.C. 608e–1) provides that when certain domestically produced commodities, including tomatoes, are regulated under a Federal marketing order, imports of that commodity must meet the same or comparable grade, size, quality, and maturity requirements. Since the proposed rule would have adjusted the exemptions to require previously exempt tomatoes to meet grade and/or size requirements, a corresponding change would have been needed to the tomato import regulations. The corresponding changes to the tomato import regulations were to be addressed in a separate rulemaking action. The comments opposed to the proposed rule focused primarily on the potential impact of changes to the tomato import regulations stemming from the changes to the domestic requirements as specified by section 8e.

The opposing comments indicated the proposed changes would increase the cost and time to bring imported tomatoes to market. Other comments expressed the proposed rule was an attempt to set up technical barriers to restrict free trade, limit fair competition and would only benefit small economic special interests. Another stated some of the proposed changes were unnecessary, as Roma tomatoes from Mexico already must meet grade requirements under the U.S.-Mexico Suspension Agreement.

Several comments objected to the definition of ''controlled environment'', stating it was trying to define production techniques that were not

used in the Florida production area. Another commenter questioned the development of the ''controlled environment'' definition, since greenhouse production methods represent a very small portion of the tomatoes handled in Florida. Comments also argued the proposed new exemption and definition were not reflective of production techniques used outside of the production area and the change would negatively impact greenhouse tomatoes. Further, one commenter stated shade-house production differs significantly from open-field tomato production, and that the structures in Mexico are permanent and provide a significant degree of control over growing conditions and warrant different treatment from open-field production.

Several commenters also expressed that certain proposed changes were inconsistent with the Act and outside the scope of the Order.

After reviewing and considering the comments received, the Agricultural Marketing Service (AMS) has determined there is little support for the proposed changes and the rule to modify the handling requirements for tomatoes grown in Florida should not be finalized. AMS intends to conduct outreach with Florida tomato industry stakeholders and consider whether changes will be proposed in the future. Accordingly, the proposed rule to modify the handling requirements in the Order that published in the **Federal Register** on June 9, 2020, (85 FR 35222) is hereby withdrawn.

List of Subjects in 7 CFR Part 966

Marketing agreements, Reporting and recordkeeping requirements, Tomatoes.

Authority: 7 U.S.C. 601–674.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2021–07730 Filed 4–14–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2020–0122]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Importation of Gypsy Moth Host Materials From Canada

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; reopening of comment period.

SUMMARY: We are reopening the comment period for our notice announcing the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the regulations to prevent the introduction of gypsy moth from Canada into noninfested areas of the United States. We are taking this action to allow interested persons the opportunity to prepare and submit comments.

DATES: The comment period for the notice published on January 21, 2021 (86 FR 6289–6290) is reopened. We will consider all comments that we receive on or before June 14, 2021.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov*. Enter APHIS–2020–0122 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2020–0122, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the importation of gypsy moth host material from Canada, contact Mr. Marc Phillips, Senior Regulatory Policy Specialist, PPQ, APHIS, USDA, 4700 River Road Unit 133, Riverdale, MD 20737; (301) 851–2114. For copies of more detailed information on the information collection, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483.

SUPPLEMENTARY INFORMATION: On January 21, 2021, we published in the **Federal Register** (86 FR 6289–6290, Docket No. APHIS–2020–0122) a notice [1] and request for comments on an information collection associated with the regulations to prevent the introduction of gypsy moth from Canada into noninfested areas of the United States.

Comments on the notice were required to be received on or before March 22, 2021. However, the docket link in the **ADDRESSES** section for submission of comments was incorrect. We are therefore reopening the comment period on Docket No. APHIS–2020–0122 for an additional 60 days to allow interested persons to prepare and submit comments.

We will also consider all comments received between March 23, 2021, (the day after the close of the comment period) and the date of this notice.

Done in Washington, DC, this 9th day of April 2021.

Mark Davidson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2021–07679 Filed 4–14–21; 8:45 am]

BILLING CODE 3410–34–P

[1] To view the notice, go to *www.regulations.gov*. Enter APHIS–2020–0122 in the Search field.

DEPARTMENT OF AGRICULTURE

Natural Resources Conservation Service

[Docket No. NRCS–2020–0008]

Proposed Revisions to the National Handbook of Conservation Practices for the Natural Resources Conservation Service

AGENCY: Natural Resources Conservation Service (NRCS), U.S. Department of Agriculture (USDA).

ACTION: Notice of availability; reopening and extension of comment period.

SUMMARY: NRCS is announcing the reopening and 2-week extension of the comment period to give the public an opportunity to provide comments on specified conservation practice standards in National Handbook of Conservation Practices (NHCP). The comment period will end on April 22, 2021.

DATES: *Comment Date:* We will consider comments that we receive by April 22, 2021. The comment period for the notice published on March 9, 2021 (86 FR 13522–13524) is reopened.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments through the:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and search for docket ID NRCS–2020–0008. Follow the instructions for submitting comments.
- *Mail, or Hand Delivery:* Mr. Clarence Prestwich, National

Agricultural Engineer, Conservation Engineering Division, NRCS, USDA, 1400 Independence Avenue, South Building, Room 4636, Washington, DC 20250. In your comment, specify the docket ID NRCS–2020–0008.

All comments will be available on *http://www.regulations.gov*.

The copies of the proposed revised standards are available through *http://www.regulations.gov* by accessing Docket No. NRCS–2020–0008. Alternatively, the proposed revised standards can be downloaded or printed from *http://go.usa.gov/TXye*.

FOR FURTHER INFORMATION CONTACT: Mr. Clarence Prestwich; telephone: (202) 720–2972; or email: *clarence.prestwich@usda.gov*.

SUPPLEMENTARY INFORMATION: NRCS is reopening and extending the comment period on the National Handbook of Conversation Practices (NHCP). The initial notice was published on March 9, 2021 (86 FR 13522–13524). The comment period closed on April 8, 2021. NRCS is reopening and extending the comment period and will accept comments received by April 22, 2021.

NRCS is planning to revise the conservation practice standards in the NHCP. The notice published March 9, 2021 (86 FR 13522–13524), included an overview of the planned changes and gives the public an opportunity to provide comments on the specific conservation practice standards that NRCS is changing.

Terry Cosby,

Acting Chief, Natural Resources Conservation Service.

[FR Doc. 2021–07686 Filed 4–14–21; 8:45 am]

BILLING CODE 3410–16–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Georgia Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Georgia Advisory Committee (Committee) will hold a meeting via web conference on Thursday, May 27, 2021, at 12:00 p.m. Eastern Time for reviewing testimony regarding civil asset forfeiture and preparing for additional hearing(s).

DATES: The meeting will be held on Thursday, May 27, 2021 at 12:00 p.m. Eastern Time.

ADDRESSES: *Register online (audio/visual): https://bit.ly/3dKRyAK.*

Join by phone (audio only):

- 800–360–9505 USA Toll Free
- Access code: 199 438 3849

FOR FURTHER INFORMATION CONTACT: Melissa Wojnaroski, DFO, at *mwojnaroski@usccr.gov* or 202–618–4158.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the above listed toll-free number. An open comment period will be provided to allow members of the public to make a statement as time allows. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Melissa Wojnaroski at *mwojnaroski@usccr.gov* in the Regional Program Unit Office/Advisory Committee Management Unit. Persons who desire additional information may contact the Regional Programs Unit Office at 202–618–4158.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Unit Office, as they become available, both before and after the meeting. Records of the meeting will be available via *https://www.facadatabase.gov* under the Commission on Civil Rights, Georgia Advisory Committee link. Persons interested in the work of this Committee are also directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Unit office at the above email or phone number.

Agenda

Welcome and Roll Call
Discussion: Civil Rights in Georgia (Civil Asset Forfeiture)
Public Comment
Adjournment

Dated: April 9, 2021.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2021–07672 Filed 4–14–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; State and Local Government Finance and Public Employment and Payroll Forms

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 27, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau.

Title: State and Local Government Finance and Public Employment and Payroll Forms.

OMB Control Number: 0607–0585.

Form Number(s): E–1, E–2, E–3, E–4, E–5, E–6, E–7, E–8, E–9, E–10, F–5, F–11, F–12, F–13, F–28, F–29, F–32.

Type of Request: Regular submission, Request for a Revision of a Currently Approved Collection.

Number of Respondents: 73,140.

Average Hours per Response: 1 hour and 41 minutes.

Burden Hours: 123,273.

Needs and Uses: The Census Bureau requests OMB approval to conduct the 2021 and 2023 Annual Surveys of State and Local Government Finances, Annual Survey of Public Employment and Payroll and the 2022 Census of Governments—Finance and Employment. We also request approval to add the collection of cannabis sales and license taxes, and sports betting sales taxes to the Annual Survey of State Tax Collections (F–5), a component of the Annual Surveys of State and Local Government Finances. This will modernize the survey's content to maintain the relevancy and sustainability of these data.

The data are released as part of the State and Local Government Finance and Public Employment & Payroll statistical series. The collections also produce individual data products that focus on state governments, local governments, and public pensions in greater detail than the combined financial and employment series as a by-product of their collections for the combined data series. The Census Bureau provides these data to the Bureau of Economic Analysis to develop the public sector components of the National Income and Product Accounts and for constructing the functional payrolls in the public sector of the Gross Domestic Product, payroll being the single largest component of current operations. The Census Bureau also provides these data to the Federal Reserve Board for use in the Flow of Funds Accounts. Other Federal agencies that make use of the data include the Council of Economic Advisers, the Agency for Healthcare Research and Quality, the Government Accountability Office, and the Department of Justice. State and local governments and related organizations, public policy groups, public interest groups, private research organizations, and private sector businesses also use these data.

Affected Public: State, Local, or Tribal government.

Frequency: Annually.

Respondent's Obligation: Voluntary.

Legal Authority: Title 13, Section 161, of the United States Code requires the Secretary of Commerce to conduct a census of governments every fifth year. Section 182 allows the Secretary of Commerce to conduct annual surveys in other years.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0585.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–07705 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Census Bureau

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Quarterly Financial Report

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 25, 2021 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: U.S. Census Bureau.

Title: Quarterly Financial Report.

OMB Control Number: 0607–0432.

Form Number(s): QFR–200(MT). QFR–201(MG), QFR–300(S).

Type of Request: Regular submission, Request for an Extension, without Change, of a Currently Approved Collection.

Number of Respondents: 8,787.

Average Hours per Response: 2 hours and 25 minutes.

Burden Hours: 84,686.

Needs and Uses: The Census Bureau is requesting Office of Management and Budget for approval, the Quarterly Financial Report (QFR) program information collection forms. The QFR forms to be submitted for approval are: The QFR 200 (MT) long form (manufacturing, mining, wholesale trade, and retail trade); QFR 201 (MG) short form (manufacturing); and the QFR 300 (S) long form (information services and professional and technical services). The Census Bureau is not requesting any changes to the current forms.

The QFR program collects and publishes up-to-date aggregate statistics on the financial results and position of U.S. corporations. The QFR target population consists of all corporations engaged primarily in manufacturing with total assets of $5 million and over, and all corporations engaged primarily in mining; wholesale trade; retail trade; information; or professional and technical services (except legal services) industries with total assets of $50 million and over.

The QFR program is a principal federal economic indicator that has published up-to-date aggregate statistics on the financial results and position of U.S. corporations since 1947. The QFR provides critical source data to the Bureau of Economic Analysis' (BEA) quarterly estimates of Gross Domestic Product (GDP) and Gross Domestic Income (GDI), key components of the National Income and Product Accounts (NIPA). The QFR data are also vital to the Federal Reserve Board's (FRB) Financial Accounts. Title 13 of the United States Code, Section 91 requires that financial statistics of business operations be collected and published quarterly. Public Law 114–72 extended the authority of the Secretary of Commerce to conduct the QFR Program under Section 91 through September 30, 2030.

The main purpose of the QFR is to provide timely, accurate data on business financial conditions for use by government and private-sector organizations and individuals. Primary public users include U.S. governmental organizations with economic measurement and policymaking responsibilities such as the Bureau of Economic Analysis, the Bureau of Labor Statistic and the Federal Reserve Board. In turn, these organizations provide guidance, advice, and support to the QFR program. The primary non-governmental data users are a diverse group including universities, financial analysts, unions, trade associations, public libraries, banking institutions, and U.S. and foreign corporations.

The Census Bureau uses two forms of data collection: Mail out/mail back paper survey forms and a secure encrypted internet data collection system called Centurion. Centurion has automatic data checks and is context-sensitive to assist respondents in identifying potential reporting problems before submission, thus reducing the need for follow-up from Census Bureau staff. Data collection through Centurion is completed via the internet, eliminating the need for downloading software and ensuring the integrity and confidentiality of the data.

Companies are asked to respond to the survey within 25 days of the end of the quarter for which the data are being requested. Census Bureau staff contact companies that have not responded by the designated time through letters, telephone calls, and/or email to encourage participation.

Affected Public: Business or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

Legal Authority: Title 13 of the United States Code, Section 91.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0607–0432.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–07706 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–827]

Certain Cased Pencils From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Determination of No Shipments, and Rescission of Review, in Part; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that Wah Yuen Stationery Co. Ltd. and Shandong Wah Yuen Stationery Co. Ltd. (collectively, Wah Yuen) had no shipments of certain cased pencils from the People's Republic of China (China) during the period of review (POR) December 1, 2018, through November 30, 2019. Commerce also preliminarily determines that Tianjin Tonghe Stationery Co., Ltd. (Tianjin Tonghe) and Ningbo Homey Union Co., Ltd. (Ningbo Homey) are part of the China-wide entity. Finally, we are rescinding the review with respect to Orient International Holding Shanghai Foreign Trade Co., Ltd. (SFTC). We invite interested parties to comment on these preliminary results.

DATES: Applicable April 15, 2021.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6478.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the initiation of this administrative review on February 6, 2020.[1] The POR is December 1, 2018, through November 30, 2019. After publication of the *Initiation Notice,* SFTC timely withdrew its request for a review,[2] and we selected Wah Yuen [3] as the sole mandatory respondent.[4]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[5] A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice.

The Preliminary Decision Memorandum is a public document and is on file electronically via the Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/.*

Scope of the Order

The merchandise subject to the order includes certain cased pencils from China. The subject merchandise is currently classifiable under Harmonized Tariff Schedule of the United States (HTSUS) subheading 9609.1010. Although the HTSUS subheading is provided for convenience and customs purposes, the written product description is dispositive. For a complete description of the scope of the order, *see* the Preliminary Decision Memorandum.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, ''in whole or in part, if a party that requested a review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review.'' SFTC withdrew its request for review within the 90-day limit. Because we received no other requests for review of SFTC, we are rescinding the administrative review with respect to SFTC.

Preliminary Determination of No Shipments

Based on an analysis of U.S. Customs and Border Protection (CBP) information and information provided by Wah Yuen, Commerce preliminarily determines that Wah Yuen had no shipments of subject merchandise during the POR.[6] For additional information regarding this determination, *see* the Preliminary Decision Memorandum. Consistent with our practice in non-market economy (NME) cases, we intend to complete the review with respect to Wah Yuen and issue appropriate instructions to CBP based on the final results of the review.[7]

China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[8] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, the

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 6896 (February 6, 2020) (*Initiation Notice*).

[2] *See* SFTC's Letter, ''Orient International Holding Shanghai Foreign Trade Co., Ltd.'s Withdrawal of Request for Review: Administrative Review of the Antidumping Duty Order on Cased Pencils from the People's Republic of China,'' dated March 9, 2020.

[3] Commerce determined that Wah Yuen Stationery Co. Ltd. and Shandong Wah Yuen Stationery Co. Ltd. are affiliated and should be treated as a single entity in prior administrative reviews. *See Certain Cased Pencils from the People's Republic of China: Preliminary Results of Antidumping Duty New Shipper Review; 2014–2015,* 81 FR 37573 (June 10, 2016), and accompanying Preliminary Decision Memorandum at 9–10, unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty New Shipper Review; 2014–2015,* 81 FR 74764 (October 27, 2016). Consistent with prior determinations, we are continuing to treat these companies as a single entity for purposes of this administrative review.

[4] *See* Memorandum, ''Antidumping Administrative Review of Certain Cased Pencils from the People's Republic of China; 2018–2019: Respondent Selection,'' dated April 24, 2020.

[5] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review: Certain Cases Pencils from the People's Republic of China; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Wah Yuen's Letters, ''Certain Cased Pencils from the People's Republic of China: Comments on CBP Entry Summary Documentation,'' dated October 12, 2020; and ''Certain Cased Pencils from the People's Republic of China: Comments on CBP Entry Summary Documentation,'' dated February 1, 2021.

[7] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65694–95 (October 24, 2011).

[8] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

entity is not under review, and the entity's rate of 114.90 percent is not subject to change.[9]

Aside from Wah Yuen, which we preliminarily find made no shipments, and SFTC, for which the review is being rescinded, Commerce considers all other companies for which a review was requested and which did not demonstrate separate rate eligibility to be part of the China-wide entity.[10] Accordingly, for the preliminary results, we consider Tianjin Tonghe and Ningbo Homey, neither of which submitted a separate rate application, to be part of the China-wide entity. For additional information, *see* the Preliminary Decision Memorandum.

Disclosure and Public Comment

Normally, Commerce discloses the calculations used in its analysis to parties in a review within five days of the date of publication of the notice of preliminary results, in accordance with 19 CFR 351.224(b). However, in this case, there are no calculations on the record to disclose.

Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review.[11] Rebuttal briefs may be filed no later than seven days after the written comments are filed, and all rebuttal comments must be limited to comments raised in the case briefs.[12] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[13]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we intend to hold the hearing at the date and time to be determined.[14] Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

Unless otherwise extended, we intend to issue the final results of this review, which will include the results of our analysis of the issues raised in any briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(h).

Assessment Rates

Upon issuance of the final results, Commerce will determine, and CBP shall assess, antidumping (AD) duties on all appropriate entries covered by this review, in accordance with 19 CFR 351.212(b). If Commerce continues to find that Tianjin Tonghe and Ningbo Homey are part of the China-wide entity in the final results, Commerce intends to instruct CBP to liquidate POR entries of subject merchandise from these companies at the China-wide rate. Moreover, if Commerce continues to make a no-shipment finding for Wah Yuen in the final results, any suspended entries of subject merchandise associated with Wah Yuen will also be liquidated at the China-wide rate. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review.

For the rescinded company SFTC, AD duties shall be assessed at rates equal to the cash deposit of estimated AD duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of this notice.

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) Wah Yuen's cash deposit rate will continue to be its existing exporter-specific rate; [15] (2) for previously investigated or reviewed Chinese and non-Chinese exporters for which a review was not requested and that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of AD duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of AD duties occurred and the subsequent assessment of double AD duties.

Notification to Interested Parties

We are issuing and publishing the preliminary results of this administrative review in accordance with sections 751(a)(l) and 777(i)(l) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: April 8, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

[9] *See Certain Cased Pencils from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission; 2014–2015,* 81 FR 83201, 83202 (November 21, 2016), unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2014–2015,* 82 FR 24675 (May 30, 2017), and accompanying Issues and Decision Memorandum.

[10] *See Initiation Notice* (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.'').

[11] *See* 19 CFR 351.309(c).

[12] *See* 19 CFR 351.309(d).

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[14] *Id.*

[15] *See Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty New Shipper Review; 2014–2015,* 81 FR 74764 (October 27, 2016), and accompanying Issues and Decision Memorandum.

VIII. Recommendation

[FR Doc. 2021–07728 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; West Coast Region Groundfish Trawl Fishery Monitoring and Catch Accounting Program

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on December 22, 2020 (85 FR 83517) during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic & Atmospheric Administration (NOAA), Commerce.

Title: West Coast Region Groundfish Trawl Fishery Monitoring and Catch Accounting Program.

OMB Control Number: 0648–0619.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 153

Average Hours per Response: For 5 existing observer providers: 2 hours for preparation and submission of the annual observer provider permit renewal application. For 1 new observer provider: 10 hours for observer provider permit application preparation and submission. For 1 observer provider: 4 hours for a written response and submission of an appeal if an observer provider permit is denied. For 45 catch monitors: 1 hour for submission of qualifications to work as a catch monitor. For 5 catch monitors: 4 hours for a written response and submission of an appeal if a catch monitor permit is denied. For 16 vessels in the Mothership or Catcher/Processor fleet, 30 minutes or less for satisfying requirements for use of at-sea scales, including daily testing reports (30 minutes), daily catch and cumulative weight reports (10 minutes), audit trail (1 minute), calibration log (2 minutes), and fault log (3 minutes).

Total Annual Burden Hours: 447 hours.

Needs and Uses: As part of its fishery management responsibilities, the National Marine Fisheries Service (NMFS) collects information to determine the amount and type of catch taken by fishing vessels. This collection supports monitoring requirements including scale test requirements for first receivers in the Pacific Coast groundfish fishery's shorebased individual fishery quota (IFQ) program; and mothership and catcher/processors in the at-sea whiting fisheries. The collection also supports permits for businesses that provide certified observer and certified catch monitor services. The respondents are principally shorebased first receivers, catch monitor and observer service providers, mothership processors, and catcher/processors, which are companies/partnerships.

Affected Public: Business or other for-profit organizations.

Frequency: Reporting on occasion, daily, weekly, or annually.

Respondent's Obligation: Mandatory.

Legal Authority: Magnuson-Stevens Fishery Conservation and Management Act.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0619.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–07743 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; West Coast Region Vessel Monitoring System Requirement in the Pacific Coast Groundfish Fishery

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 11, 2021, (86 FR 1947), during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA), Commerce.

Title: West Coast Region Vessel Monitoring System Requirement in the Pacific Coast Groundfish Fishery.

OMB Control Number: 0648–0573.

Form Number(s): N/A.

Type of Request: Regular submission (revision of a current information collection).

Number of Respondents: 1,000.

Average Hours per Response: Four hours to install and activate a VMS unit; one hour to maintain a VMS unit, five minutes to complete and fax a check-in report or to complete an exemption report; four minutes for a declaration report.

Total Annual Burden Hours: 2,021.

Needs and Uses: This is a request for a revision and extension of a currently approved information collection. The National Marine Fisheries Service (NMFS) implemented a Vessel Monitoring Program in 2004, consistent with the Magnuson-Stevens Fishery Conservation and Management Act (MSA) and the Pacific Coast Groundfish Fishery Management Plan (FMP). Under this program described at 50 CFR 660.13 and 660.14, all commercial fishing vessels fishing in the exclusive economic zone off the West Coast that take and retain groundfish in federal waters, or transit through federal waters

with groundfish on board, are required to have a working vessel monitoring system (VMS). To support the VMS monitoring program, the following information must be submitted to NMFS: (1) VMS installation/activation certification reports, (2) position reports, (3) exemption reports, and (4) declaration reports. The VMS, along with the fishing declaration reporting requirements, allows for monitoring and enforcement of areas closed to fishing by gear type as traditional enforcement methods (such as aerial surveillance, boarding at sea via patrol boats, landing inspections and documentary investigation) are especially difficult to use when the closed areas are large-scale and the lines defining the areas are irregular.

The collection is being revised to remove the position report from the collection with regard to burden. The position reports are automatically transmitted location signals from the VMS unit that do not require any action on the part of the captain or crew.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Installation/Activation/Maintenance once every four years; exemption reports are optional (estimated 2/year for 500 participants); declaration reports are estimated to be sent by each participant 20 times per year.

Respondent's Obligation: Mandatory.

Legal Authority: 50 CFR 660.13 and 660.14.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0573.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–07750 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Alaska Chinook Salmon Economic Data Report (EDR)

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice. We invite the general public and other Federal agencies to comment on proposed, and continuing information collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. Public comments were previously requested via the **Federal Register** on January 13, 2021 (86 FR 2646), during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Alaska Chinook Salmon Economic Data Report (EDR).

OMB Control Number: 0648–0633.

Form Number(s): None.

Type of Request: Regular submission (extension of a current information collection).

Number of Respondents: 150.

Average Hours per Response: Compensated Transfer Report: 40 hours; Vessel Fuel Survey: 4 hours; Vessel Master Survey: 4 hours; CTR Verification Audit: 4 hours.

Total Annual Burden Hours: 600 hours.

Needs and Uses: The National Marine Fisheries Services (NMFS), Alaska Regional Office, is requesting extension of the currently approved information collection for the Alaska Chinook Salmon Economic Data Report (the EDR). The EDR collects economic data for the Alaska Chinook Salmon Economic Data Report Program.

NMFS manages the Bering Sea pollock fishery under the American Fisheries Act (AFA) (16 U.S.C. 1851). AFA fishing vessels harvest pollock in the Bering Sea pollock fishery using pelagic (midwater) trawl gear, which consists of large nets towed through the water by the vessel. At times, Chinook salmon and pollock occur in the same locations in the Bering Sea; consequently, Chinook salmon are incidentally caught in the nets as pollock is harvested. This incidental catch is called bycatch and is also called prohibited species catch (PSC).

The EDR Program provides NMFS and the North Pacific Fishery Management Council (Council) with data to evaluate the effectiveness of Chinook salmon bycatch management measures for the Bering Sea pollock fishery that were implemented under Amendment 91 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (75 FR 53026, August 30, 2010). The EDR consists of three data collections that are submitted annually by owners and operators of catcher vessels, catcher/processors, motherships, and the Western Alaska Community Development Quota Program groups qualified to participate in the Bering Sea pollock fishery (50 CFR 679.65). The EDR Program also includes a means for NMFS to verify the data submitted in these three collections.

NMFS and the Council use the information to determine the effectiveness of the Incentive Plan Agreement (IPA) (see OMB Control No. 0648–0401), the IPA incentives, the PSC limits, and the performance standard in terms of minimizing salmon bycatch in times of high and low levels of salmon abundance. NMFS and the Council also use the data to evaluate how Amendment 91 affects where, when, and how pollock fishing and salmon bycatch occur and to study and verify conclusions drawn by industry in the IPA annual reports.

The EDR is submitted annually by each person who held AFA pollock quota share in the previous calendar year or was an owner or leaseholder of an AFA permitted vessel in the previous calendar year.

The EDR requirements are located at 50 CFR 679.65.

Affected Public: Individuals or households; Business or other for-profit organizations.

Frequency: Annually.

Respondent's Obligation: Mandatory

Legal Authority: American Fisheries Act (16 U.S.C. 1851); Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/*

public/do/PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0648–0633.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Chief Information Officer, Commerce Department.

[FR Doc. 2021–07742 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. PTO–P–2021–0019]

Fast-Track Pilot Program for Appeals Related to COVID–19

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO) is initiating the Fast-Track Pilot Program for Appeals Related to COVID–19 to provide for the advancement of applications out of turn in ex parte appeals related to COVID–19 before the Patent Trial and Appeal Board (PTAB). An appellant who has filed an ex parte appeal of an application with claim(s) that cover a product or process related to COVID–19 (such product or process must be subject to an applicable U.S. Food and Drug Administration (FDA) approval for COVID–19 use) and received a notice that the appeal has been docketed may file a petition at no cost to expedite the review of his or her appeal without paying a petition fee. The Fast-Track Pilot Program for Appeals Related to COVID–19 sets a target of reaching a decision on an ex parte appeal within six months from the date the appeal is entered into the pilot program.

DATES: *Applicability Date:* Petitions for the pilot program can be filed starting on April 15, 2021. *Duration:* The Fast-Track Pilot Program for Appeals Related to COVID–19 is offered on a temporary basis, and petitions to request inclusion of an ex parte appeal in the pilot program will be accepted until 500 appeals have been accorded fast-track status under the program. The USPTO may extend the Fast-Track Pilot Program for Appeals Related to COVID–19 (with or without modification) or may terminate it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program. If the pilot program is extended or terminated, the USPTO will notify the public.

FOR FURTHER INFORMATION CONTACT: Steven Bartlett, PTAB, by telephone at 571–272–9797, or by email at *COVIDfasttrackappeals@uspto.gov.*

SUPPLEMENTARY INFORMATION:

Background

Appeals to the PTAB are normally taken up for decision in the order in which they are docketed. *See* USPTO Standard Operating Procedure 1 (Sept. 20, 2018), available at *www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/resources.* Currently, the average appeal pendency is about 13 months. *See* PTAB Statistics, available at *www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/statistics.* However, a small number of appeals are advanced out of turn due to a special status. For example, reexamination proceedings, which are handled by the USPTO with ''special dispatch,'' and reissue applications are treated as special throughout their pendency, including during appeal. *See* Manual of Patent Examining Procedure (MPEP) 708.01. Applications that have been ''made special'' during examination through a petition based on the age or health of an applicant, or for other reasons listed in 37 CFR 1.102 (a)–(d), also maintain their special status through any appeal. *See* MPEP 1203(II). Furthermore, for the same reasons, an appellant may petition the PTAB to have an application on appeal made special. *See id.* Currently, about 1.1% of appeals are given a special status through one of the above methods.

Recently, the PTAB instituted the Fast-Track Appeals Pilot Program, in which the PTAB accepts petitions for advancing out of turn and according fast-track status to ex parte appeals that have already been docketed. 85 FR 39888 (July 2, 2020). This pilot program began on July 2, 2020 and will continue for one year or until 500 appeals have been accorded fast-track status under the program. An appellant can seek fast-track status by submitting a petition to the Chief Administrative Patent Judge under 37 CFR 41.3 and paying the fee required under 37 CFR 41.20(a), currently $420. The Fast-Track Appeals Pilot Program sets a target of reaching a decision on the ex parte appeal within six months from the date an appeal is entered into the pilot program. More information on the Fast-Track Appeals Pilot Program can be found at *www.uspto.gov/patents/ptab/fast-track-appeals-pilot-program.*

In an extraordinary situation, 37 CFR 1.183 permits the USPTO to suspend or waive sua sponte any requirement of its regulations that is not a requirement of the patent statutes. The USPTO considers the effects of the COVID–19 pandemic that began in approximately January 2020 to be an ''extraordinary situation'' within the meaning of 37 CFR 1.183 for affected patent applicants and innovators. Consistent with the USPTO's determination under 37 CFR 1.183, the provisions of 35 U.S.C. 2(b)(2)(G), and the COVID–19 Prioritized Examination Pilot Program, the USPTO has decided to implement the Fast-Track Pilot Program for Appeals Related to COVID–19, under which an appellant may have any ex parte appeal to the PTAB accorded fast-track status by filing a petition under 37 CFR 41.3, without payment of the petition fee under 37 CFR 41.20(a), for certain applications that claim products or processes that are subject to an applicable FDA approval for COVID–19 use. Such approvals may include, but are not limited to, an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA). Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at *www.fda.gov.*

The Fast-Track Pilot Program for Appeals Related to COVID–19 will accept petitions for advancing out of turn and according fast-track status to ex parte appeals until 500 appeals have been accorded fast-track status under the program. There is no time limit for receipt of these 500 COVID–19 related appeals. Additionally, the 500-appeal threshold for COVID–19 related appeals is distinct from the 500-appeal threshold used for the regular fast-track appeals pilot. The threshold of 500 granted petitions corresponds to approximately 8% of the total number of new appeals received in the average fiscal year and was chosen in accordance with maintaining the PTAB's overall decision pendency goals. Once the threshold of 500 granted petitions is met, the USPTO may extend the Fast-Track Pilot Program for Appeals Related to COVID–19 (with or without modification) or may discontinue it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program.

Requirements for Entry Into the Pilot Program

The PTAB will accord fast-track status to a pending ex parte appeal under the following conditions:

(1) The application must be an original utility, design, or plant nonprovisional application. The Fast-Track Pilot Program for Appeals Related to COVID–19 is not available for applications or proceedings that are already treated as special during appeal, such as reissue applications, reexamination proceedings, appeals made special due to the age or health of an applicant, or appeals subject to any other pilot program that advances an appeal out of turn, including the Fast-Track Appeals Pilot Program. *See* MPEP 708.01 for a complete list of cases that are treated as special.

(2) Petition Requirements.

A petition under 37 CFR 41.3 must be filed in the application involved in the ex parte appeal for which fast-track status is sought and must identify that application and appeal by application number and appeal number, respectively. *See* MPEP 502.05. The petition may be submitted via: (1) The USPTO patent electronic filing systems (EFS-Web or Patent Center), (2) the U.S. Postal Service by Priority Mail Express under 37 CFR 1.10 or with a certificate of mailing under 37 CFR 1.8, or (3) hand-delivery to the USPTO Customer Service Window (MPEP 501). Electronic submission of a petition is preferred for faster petition processing. In addition, the appeal for which fast-track status is sought must be an appeal for which a notice of appeal has been filed under 37 CFR 41.31 and an appeal docketing notice has been mailed by the PTAB.

The petition must certify that the application involved in the appeal claims products or processes that are subject to an applicable FDA approval for COVID–19 use. Such approvals may include, but are not limited to, an IND application, an IDE, an NDA, a BLA, a PMA, or an EUA. Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at *www.fda.gov.*

The USPTO has created a form-fillable Portable Document Format (PDF), ''Petition—Fast-Track Pilot Program for Appeals Related to COVID–19'' (Form PTO/SB/454), that is recommended for filing a petition under 37 CFR 41.3 for the Fast-Track Pilot Program for Appeals Related to COVID–19. Form PTO/SB/454 is available on the USPTO's website (*www.uspto.gov/patent/patents-forms*). Form PTO/SB/454 contains all necessary certifications for participation in the program. Form PTO/SB/454 does not collect ''information'' within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). *See* 5 CFR 1320.3(h). Therefore, this notice does not involve information collection requirements that are subject to review by the Office of Management and Budget. It is recommended, but not required, that appellants use Form PTO/SB/454 when petitioning for entry into the Fast-Track Pilot Program for Appeals Related to COVID–19. Any petition filed by any means other than Form PTO/SB/454 must still contain the required information.

(3) Signature Requirements.

The petition under 37 CFR 41.3 must be signed by an applicant who is prosecuting the applicant's own case under 37 CFR 1.31 (except that a juristic entity must be represented by a registered practitioner even if the juristic entity is the applicant), a registered practitioner who has a power of attorney under 37 CFR 1.32, or a registered practitioner who has the authority to act under 37 CFR 1.34, in order for the application involved in the appeal to be accorded fast-track status.

(4) Fee.

The petition fee ordinarily required under 37 CFR 41.20(a) will be waived pursuant to 37 CFR 1.183.

(5) Limit on Number of Ex Parte Appeals Accorded Fast-Track Status.

The number of granted petitions in the Fast-Track Pilot Program for Appeals Related to COVID–19 is limited to a total of 500 granted petitions.

The threshold of 500 granted petitions has been chosen to allow for robust participation in the Fast-Track Pilot Program for Appeals Related to COVID–19 without compromising the PTAB's ability to deliver on other appeal pendency goals. The limit of 500 granted petitions corresponds to approximately 8% of the total number of new appeals received in the average fiscal year. The USPTO may modify or terminate the pilot program depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program.

Handling of Petitions in the Fast-Track Pilot Program for Appeals Related to COVID–19

Petitions for entry into the Fast-Track Pilot Program for Appeals Related to COVID–19 will be decided in the order they are received. Petitions meeting the requirements listed above for entry into the pilot program will be granted, and the petitioner will be notified by a decision granting the petition to accord fast-track status. Petitions not meeting the requirements listed above for entry into the pilot program will be denied, and the petitioner will be notified of a decision denying the petition. A petitioner may reapply if a first petition is denied. Any second petition filed by a petitioner for the same application and same appeal covered by a first, failed petition will not be accorded the filing date of the first petition for purposes of determining whether the second petition fell within the threshold of 500 granted petitions.

The PTAB will communicate the number of granted petitions for fast-track appeal via the PTAB web page, *www.uspto.gov/PTABCOVIDFastTrack,* and appellants should take this information into account when deciding whether to file a petition. The PTAB may also exercise discretion to grant a small number of petitions in excess of the threshold of 500 granted petitions.

Conduct of Fast-Track Pilot Program for Appeals Related to COVID–19

(1) Time to Decision

The goal for rendering a decision on the petition to accord fast-track status to an ex parte appeal is no later than one month from the filing date of the petition. The goal for rendering a decision on the ex parte appeal is no later than six months from the date an appeal is entered into the program, which occurs when a petition to accord fast-track status to the appeal is granted.

(2) When a Petition May Be Filed

A petition may be filed anytime between (1) the date when the PTAB issues a notice that the appeal has been docketed to the PTAB, and (2) the date at which the appellant withdraws the appeal, a final decision is rendered by the PTAB under 37 CFR 41.50, or PTAB jurisdiction ends under 37 CFR 41.35. Petitions for fast-track status may be filed for ex parte appeals regardless of whether the appeal is newly docketed or was docketed previously. If the petition complies with the formal requirements (*i.e.,* signature, identification of application, certification that the application claims a product or process subject to an applicable FDA approval for COVID–19 use), the appeal will be given fast-track status in accordance with current procedures, including the overall program threshold described above.

(3) Hearings

Inclusion in the Fast-Track Pilot Program for Appeals Related to COVID–19 may be requested for ex parte appeals in which the appellant seeks an oral hearing before the PTAB (heard appeals), as well as those appeals for

which no oral hearing is requested (on-brief appeals). Hearings in ex parte appeals accorded fast-track status under the pilot program will be conducted according to the ordinary PTAB hearing procedures. Appellants seeking an oral hearing should submit with the request for oral hearing any preferences as to the time, date, or location of the hearing. The PTAB will make its best efforts to schedule a hearing in accordance with such preferences, consistent with the goals of the pilot program. If the PTAB is unable to accommodate an appellant's preferences, the PTAB will schedule the hearing in an available hearing room at any office, including a regional office, and at a time and date best suited to meeting the goals of the pilot program. If no such hearing room is available, the PTAB will schedule a hearing to be conducted by videoconference or telephone.

Because an appellant seeks a faster decision and hearing room availability is limited, an appellant in an ex parte appeal accorded fast-track status may not seek to relocate (to a different office) the hearing after receiving a Notice of Hearing. An appellant who does not wish to attend the hearing at the designated location may, however, request to attend the hearing by videoconference or telephone, in accordance with current PTAB hearing procedures. An appellant may also waive the hearing and continue under the Fast-Track Pilot Program for Appeals Related to COVID–19 for consideration and decision on the briefs.

An appellant may not reschedule the date or time of a hearing and remain in the Fast-Track Pilot Program for Appeals Related to COVID–19. If an appellant in an ex parte appeal accorded fast-track status must reschedule the date or time of a hearing and is not willing to waive the oral hearing, then the appellant may opt out of the Fast-Track Pilot Program for Appeals Related to COVID–19, thereby regaining the ability to reschedule or relocate the hearing as per ordinary PTAB hearing procedures.

(4) Termination of Fast-Track Status Under the Fast-Track Pilot Program for Appeals Related to COVID–19

Fast-track status will be maintained in an ex parte appeal from the date at which the petition for inclusion in the Fast-Track Pilot Program for Appeals Related to COVID–19 is granted until the PTAB's jurisdiction ends under 37 CFR 41.35(b). Activities subsequent to an appellant's withdrawal from the pilot program or the PTAB's decision, including any reopened prosecution, will not be treated as subject to fast-track status, nor will filing a petition for inclusion in the Fast-Track Pilot Program for Appeals Related to COVID–19 cause an application to be accorded fast-track status outside the jurisdiction of the PTAB. Additionally, any request by an appellant that causes a delay in the conduct of the appeal, such as for an extension of time under 37 CFR 1.136(b), or for additional briefing, will be cause for the removal of fast-track status.

Status of the Pilot Program

The Fast-Track Pilot Program for Appeals Related to COVID–19 is being adopted on a temporary basis until 500 appeals have been accorded fast-track status under the program. The USPTO may extend the Fast-Track Pilot Program for Appeals Related to COVID–19 (with or without modification) or may discontinue the pilot program depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program.

The USPTO will notify the public when the threshold of 500 granted petitions for the Fast-Track Pilot Program for Appeals Related to COVID–19 is about to be reached, and with any further relevant information, on the PTAB web page at *www.uspto.gov/PTABCOVIDFastTrack.*

Andrew Hirshfeld,

Commissioner for Patents, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2021–07704 Filed 4–14–21; 8:45 am]

BILLING CODE 3510–16–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2020–0027]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Warning Label Comprehension and Interpretation by Consumers for Children's Sleep Environments

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required under the Paperwork Reduction Act of 1995 (PRA), the Consumer Product Safety Commission (CPSC or Commission) announces that CPSC has submitted to the Office of Management and Budget (OMB) a new proposed collection of information for a survey that will evaluate consumer awareness of infant sleep product warning labels. On December 21, 2020, the CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of this collection of information. After reviewing and considering the comments, the Commission announces that it has submitted to the OMB a request for approval of this collection of information. A copy of the proposed survey, ''Revised Supporting Statement'' titled *Consumer Product Safety Commission: Warning Label Comprehension and Interpretation by Consumers for Children's Sleep Environments,* is available at: *www.regulations.gov* under Docket No. CPSC–2020–0027, Supporting and Related Material.

DATES: Submit written or electronic comments on the collection of information by May 17, 2021.

ADDRESSES: Send written comments and recommendations for the proposed information collection within 30 days of publication of this notice to: *www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting, ''Currently under 30-day Review—Open for Public Comments,'' or by using the search function. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2020–0027.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7991, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

Under the Paperwork Reduction Act of 1995 (PRA; 44 U.S.C. 3501–3520), federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency data-collection studies. The PRA establishes procedures agencies must follow to obtain OMB approval of a collection of information, including notice and a review of comments, among other procedures. Agencies must provide notice of the proposed collection of information in the **Federal Register**, and provide a 60-day comment period, before submitting the collection to OMB for approval. 44 U.S.C. 3506(c)(2)(A). Agencies then must evaluate any public

comments and publish another notice in the **Federal Register**. *Id.* 3507(a)(1).

In accordance with these procedures, on December 21, 2020, CPSC published a notice in the **Federal Register** announcing the agency's intent to seek approval of a new collection of information on a survey on Warning Label Comprehension and Interpretation by Consumers for Children's Sleep Environments. 85 FR 83066. Section D. Comments, below, summarizes and addresses the comments CPSC received.

B. Warning Label Comprehension Survey

CPSC is authorized under section 5(a) of the Consumer Product Safety Act (CPSA), 15 U.S.C. 2054(a), to conduct studies and investigations relating to the causes and prevention of deaths, accidents, injuries, illnesses, other health impairments, and economic losses associated with consumer products. Section 5(b) of the CPSA, 15 U.S.C. 2054(b), further provides that CPSC may conduct research, studies, and investigations on the safety of consumer products, or test consumer products and develop product safety test methods and testing devices.

In 2019, the CPSC published the 2019 Nursery Product Annual Report, which reported injuries and deaths associated with nursery products among children younger than age 5.[1] That report identified 320 deaths related to nursery products from 2014 through 2016. Infant sleep products were associated with the most deaths: Cribs/mattresses (33%), cradles/bassinets (18%), and playpens/play yards (20%). Also, in 2019, CPSC conducted a focus group of 48 participants to gather feedback from parents and grandparents (caregivers) on their beliefs, experience, and perceptions about infant sleeping practices and caregivers' compliance with safety messaging on nursery products. Caregiver responses in the focus group study indicated limited adherence to infant sleep safety warning messaging.[2] Some of the reasons for lack of adherence to safety warnings include caregiver perceptions that warning labels contain repetitive, non-specific information that fails to target the safety hazard. Additionally, caregivers are inundated with safety messaging that changes constantly, resulting in ambiguity about what messages are most relevant and current. Product marketing and the proliferation of new products may confuse caregivers as well. Caregivers often end up listening to friends and family, or relying on past experience, to decide what behaviors are safe for their child, rather than follow the current guidelines recommended by experts. If caregivers are not attuned to the safety messaging on new products, they are more likely to use the products incorrectly.

Accordingly, CPSC seeks to learn more about consumers' understanding of specific warning labels related to products that may be used as a sleeping environment for infants and how those labels influence caregivers' behavior. In the proposed information collection, CPSC seeks to survey 650 caregivers to obtain information regarding the gap in consumer knowledge about product warning labels and consumer adherence to, and behaviors associated with, warning labels. The online survey will be conducted with caregivers age 18 and above, who are a parent or a grandparent with a child/grandchild from 2 months to 11 months old.

CPSC has contracted with Fors Marsh Group, LLC, to develop and execute this project for CPSC. If CPSC can obtain information through the survey about caregiver perceptions and comprehension of warning label language, CPSC will be able to identify better the types of safety warning labels and safety messaging that are unclear to the target audience, and that potentially serve as a barrier to safe sleep. Information obtained through this survey is not intended to be nationally representative. CPSC intends to use findings from this survey, in conjunction with findings from other research and activities, to assist with providing recommendations for refining and enhancing warning labels in the future.

C. Burden Hours

We estimate the number of respondents to the survey to be 650. The online survey for the proposed study will take approximately 15 minutes (0.25 hours) to complete. We estimate the total annual burden hours for respondents to be 162.50 hours. The monetized hourly cost is $36.22, as defined by total compensation for all civilian workers, U.S. Bureau of Labor Statistics, Employer Costs for Employee Compensation, as of March 2020. Accordingly, we estimate the total cost burden to be $5,885.75 (162.50 hours × $36.22). The total cost to the federal government for the contract to design and conduct the proposed survey is $150,987.

D. Comments

CPSC received three comments in response to the notice of December 21, 2020. All three commenters supported the information collection and made additional suggestions regarding the survey.

One commenter recommended ensuring that ''at-risk populations'' will be included in the survey. This commenter also recommended that the pool of eligible responders be broadened to include other family members and childcare providers. The survey currently is designed to obtain a mix demographics of responders, including members of at-risk populations, but it does not have specific percentages of groups allocated. Since the information obtained through this project is not intended to be nationally representative, but rather, designed generally to inform CPSC about caregiver perceptions and comprehension of warning label language, CPSC believes the current design of mixed demographics is sufficient.

The same commenter also recommended that the survey be conducted in multiple languages, use easy-to-understand language, and use pictures. The survey is already designed using clear, easy-to-understand language; however, pictograms are not used or contemplated in this survey. The use of pictograms would require a different type of survey, due to the need to test and verify the pictograms for understandability, and that is outside the scope of this survey. However, the CPSC may consider future surveys, with targeted audiences of interest, to obtain information that will help CPSC refine and optimize labels.

Another commenter recommended that the messaging in the warnings should align with the American Academy of Pediatrics' (AAP) evidence-based safe sleep recommendations that babies should be placed alone to sleep in a crib, bassinet, or play yard that meets current federal standards; on a firm, flat surface in their own space; and with no restraints or extra bedding. CPSC staff seeks to identify ways to increase caregiver understanding and adherence to infant product warning labels, which, in turn, may potentially reduce the incidence of infant sleep-related deaths in the future. Therefore, the warning messages on the example labels do not contradict AAP infant safe sleep recommendations. This commenter also stated that warning labels should not be used as substitutes for safe product design. CPSC staff agrees that in the hierarchy of safety, warnings are not a substitute for safe

[1] *https://www.cpsc.gov/s3fs-public/Nursery%20Products%20Annual%20Report%20Dec2019_2.pdf*? TkU_cVyVv69sq6Lpx0aSRjoLomqXWxRq.

[2] *https://www.reginfo.gov/public/do/PRAViewIC?ref_nbr=201909-3041-002&icID=234760.*

product design, but when attached to infant products, warnings are useful, because they can serve to remind caregivers of the safety warnings while caregivers are using the products.

A third commenter requested that the information provided in the survey clearly distinguish between products intended for overnight and unattended sleep, and those designed for other activities, including napping. CPSC agrees this distinction will help clarify the question for caregivers. Accordingly, CPSC has revised the following question in the survey: ''Which of the following product(s) do you use to put your infant to sleep'' into two separate questions: (1) Which of the following products do you use to put your infant to sleep overnight?; and (2) Which of the following products do you use to put your infant in for supervised use, including napping? In addition, CPSC has changed the references throughout the survey from: ''Warnings on Infant Sleep Products,'' to: ''Warnings on Infant Products,'' to cover warning labels that might be intended for overnight and unattended sleep, as well as infant products designed for other activities.

This commenter also stated that asking responders a question about whether they ''like'' or ''dislike'' a warning label is inappropriate, and they suggested that it is more appropriate to ask about effectiveness of warning labels. CPSC agrees that seeking a response on the ''likeability'' of the warning label may not elicit a meaningful response. Accordingly, this question has been deleted from the survey. A copy of the proposed survey, ''Revised Supporting Statement'' titled *Consumer Product Safety Commission: Warning Label Comprehension and Interpretation by Consumers for Children's Sleep Environments,* is available at: *www.regulations.gov* under Docket No. CPSC–2020–0027, Supporting and Related Material.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2021–07707 Filed 4–14–21; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3273–024]

Chittenden Falls Hydropower, Inc.; Notice of Waiver Period for Water Quality Certification Application

On March 24, 2021, Chittenden Falls Hydropower, Inc. notified the Federal Energy Regulatory Commission that on March 8, 2021, it submitted a pre-filing meeting request, pursuant to 40 CFR 121.4, together with an application for a Clean Water Act section 401(a)(1) water quality certification to the New York State Department of Environmental Conservation (New York DEC), in conjunction with the above captioned project. Pursuant to 40 CFR 121.6, we hereby notify New York DEC of the following:

Date of Receipt of the Certification Request: April 7, 2021.[1]

Reasonable Period of Time to Act on the Certification Request: One year.

Date Waiver Occurs for Failure to Act: April 7, 2022.

If New York DEC fails or refuses to act on the water quality certification request by the above waiver date, then the agency certifying authority is deemed waived pursuant to section 401(a)(1) of the Clean Water Act, 33 U.S.C. 1341(a)(1).

Dated: April 8, 2021.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2021–07684 Filed 4–14–21; 8:45 am]

BILLING CODE 6717–01–P

[1] 40 CFR 121.4(a) requires that a project proponent request a meeting with the state certifying authority to discuss the project at least 30 days prior to submitting a certification request. Here, Chittenden Falls Hydropower, Inc. submitted its request for a pre-filing meeting on March 8, 2021, which was the same date it submitted its section 401 application to New York DEC. To account for the 30-day period associated with the pre-filing meeting request and to render the certification request compliant with 40 CFR 121.5(b), the date of receipt of the certification request is 30 days after the pre-filing meeting was requested, *i.e.,* April 7, 2021.

DEPARTMENT OF ENERGY

Western Area Power Administration

Boulder Canyon Project

AGENCY: Western Area Power Administration, DOE.

ACTION: Notice of proposed fiscal year 2022 Boulder Canyon Project base charge and rates for electric service.

SUMMARY: The Desert Southwest Region (DSW) of the Western Area Power Administration (WAPA) is proposing an adjustment to the base charge and rates for fiscal year (FY) 2022 Boulder Canyon Project (BCP) electric service under Rate Schedule BCP–F10. The proposal would increase the base charge 9 percent from $65.4 million in FY 2021 to $71.3 million in FY 2022. The change is primarily the result of an increase in Bureau of Reclamation's (Reclamation) replacement costs, an increase in WAPA's operations and maintenance expenses and replacement costs, and a decrease in prior year carryover funds from FY 2021. The proposed base charge and rates would go into effect on October 1, 2021 and remain in effect through September 30, 2022. Publication of this **Federal Register** notice will initiate the public process.

DATES: The consultation and comment period begins today and will end July 14, 2021. DSW will present a detailed explanation of the proposed FY 2022 base charge and rates at a public information forum that will be held on May 17, 2021, from 10 a.m. to 12 p.m. Mountain Standard Time. DSW will also host a public comment forum that will be held on June 14, 2021, from 10 a.m. to 12 p.m. Mountain Standard Time. DSW will conduct both the public information forum and the public comment forum via Webex. Instructions for participating in the forums will be posted on DSW's website at least 14 days prior to the public information and comment forums at *https://www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx*. DSW will accept written comments any time during the consultation and comment period.

ADDRESSES: Send written comments to Mr. Jack D. Murray, Acting Regional Manager, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, Arizona 85005–6457, or *dswpwrmrk@wapa.gov*. DSW will post information concerning the rate process and written comments received on its website at *https://www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx*.

FOR FURTHER INFORMATION CONTACT: Ms. Tina Ramsey, Rates Manager, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, Arizona 85005–6457, (602) 605–2565, or *dswpwrmrk@wapa.gov*.

SUPPLEMENTARY INFORMATION: Hoover Dam,[1] authorized by the Boulder

[1] Hoover Dam was known as Boulder Dam from 1933 to 1947, but was renamed Hoover Dam by an

Continued

Canyon Project Act of 1928, as amended (43 U.S.C. 617 *et seq.*), sits on the Colorado River along the Arizona-Nevada border. The Hoover Dam power plant has 19 generating units (two for plant use) and an installed capacity of 2,078.8 megawatts (4,800 kilowatts for plant use). In collaboration with Reclamation, WAPA markets and delivers hydropower from the Hoover Dam power plant through high-voltage transmission lines and substations to Arizona, Southern California, and Southern Nevada.

The rate-setting methodology for BCP calculates an annual base charge rather than a unit rate for Hoover Dam hydropower. The base charge recovers an annual revenue requirement that includes projected costs of investment repayment, interest, operations, maintenance, replacements, payments to States, and Hoover Dam visitor services. Non-power revenue projections such as water sales, Hoover Dam visitor revenue, ancillary services, and late fees help offset these projected costs. Hoover power customers are billed a percentage of the base charge in proportion to their power allocation. A unit rate is calculated for comparative purposes but is not used to determine the charge for service.

On June 6, 2018, the Federal Energy Regulatory Commission (FERC) confirmed and approved Rate Schedule BCP–F10 for a 5 year period ending September 30, 2022.[2] Rate Schedule BCP–F10 and the BCP Electric Service Contract require WAPA to determine the annual base charge and rates for the next fiscal year before October 1 of each year. The FY 2021 BCP base charge and rates expire on September 30, 2021.

COMPARISON OF BASE CHARGE AND RATES

	FY 2021	FY 2022	Amount change	Percent change
Base Charge ($)	$65,443,462	$71,315,922	$5,872,460	9.0
Composite Rate (mills/kWh)	18.10	19.72	1.62	9.0
Energy Rate (mills/kWh)	9.05	9.86	0.81	9.0
Capacity Rate ($/kW-Mo)	$1.69	$1.84	0.15	8.9

Reclamation's FY 2022 budget is increasing $3.6 million to $83.7 million, a 4.4 percent increase from FY 2021. While operations and maintenance costs are decreasing $3.3 million compared to FY 2021, replacement costs are increasing $5.3 million due to the inclusion of projects that were deferred in FY 2020 and FY 2021 due to the COVID–19 pandemic as well as the addition of projects that are beginning in FY 2022. These projects include 480-volt switchgear replacement, water plant and wastewater plant controls replacement, wastewater treatment facility replacement, escalator replacement, additional tail bay stop log installation, central section HVAC replacement, Cisco optical networking services upgrade, and N7 unit oil system replacement. Visitor services costs also are increasing by $1.5 million in FY 2022, primarily due to a $1 million reallocation of expenses from administrative and general expenses in operations and maintenance to visitor services expenses. Higher labor projections in salaries, overtime, overhead, and benefits also contribute to the visitor services increase.

WAPA's FY 2022 budget is increasing $762,000 to $9.2 million, a 9.1 percent increase from FY 2021. A $247,000 increase in WAPA's replacement budget for communication equipment, as well as higher operations and maintenance expenses of $520,000, account for this increase. The increase in operations and maintenance expenses is primarily due to the Hoover-Mead transmission line lease costs, which were not budgeted in FY 2021; an updated distribution of labor costs resulting from the closure of the Navajo Generating Station near Page, Arizona; and higher labor projections for salaries, overtime, overhead, and benefits in power operations. The increase in replacements and operations and maintenance costs is offset by a modest decrease in facility expenses and post-retirement benefits.

The cost increase for both Reclamation and WAPA is offset by a $2.1 million increase in non-power revenue projections due to the added commercial use authorization for road-based tours. Prior year carryover is estimated to be $684,000, a $3.6 million decrease from FY 2021.

The composite and energy rates are both increasing 9 percent from FY 2021. The composite and energy rates use a forecasted energy value. The capacity rate is increasing 8.9 percent from FY 2021 due to the increase in the base charge. Forecasted energy and capacity values may be updated when determining the final base charge if hydrological conditions change.

This proposed rate adjustment, which would be effective October 1, 2021, is preliminary and subject to change based on modifications to forecasts before publication of the final base charge and rates.

Legal Authority

This action constitutes a major rate adjustment as defined by 10 CFR 903.2(e). Pursuant to 10 CFR 903.15 and 10 CFR 903.16, DSW will hold public information and public comment forums for this rate adjustment. DSW will review and consider all timely public comments at the conclusion of the consultation and comment period and make adjustments to the proposal as appropriate.

WAPA is establishing rates for BCP electric service in accordance with section 302 of the Department of Energy (DOE) Organization Act (42 U.S.C. 7152). This provision transferred to, and vested in, the Secretary of Energy certain functions of the Secretary of the Interior, along with the power marketing functions of Reclamation. Those functions include actions that specifically apply to the BCP.

The BCP Electric Service Contract states that for years other than the first year and each fifth year thereafter, when the rate schedule is approved by the Deputy Secretary on a provisional basis and by FERC on a final basis, adjustments to the base charge ''shall be effective upon approval by the Deputy Secretary of Energy.'' Under the DOE Organization Act, the Secretary of Energy holds plenary authority over DOE affairs with respect to the Power Marketing Administrations, and the Secretary of Energy may therefore exercise the Deputy Secretary's

April 30, 1947 joint resolution of Congress. *See* Act of April 30, 1947, H.J. Res. 140, ch. 46, 61 Stat. 56–57.

[2] Order Confirming and Approving Rate Schedule on a Final Basis, FERC Docket No. EF18–1–000, 163 FERC ¶ 62,154 (2018).

contractual authority in this context. By Delegation Order No. S1–DEL–S4–2021, effective February 25, 2021, the Acting Secretary of Energy delegated to the Under Secretary for Science (and Energy) the authority vested in the Secretary with respect to WAPA. By Redelegation Order No. 00–002.10E, effective February 14, 2020, the Under Secretary of Energy (to whom such authority was delegated by the Secretary of Energy in Delegation Order No. 00–002.00S from January 15, 2020 until that delegation was rescinded on February 25, 2021) redelegated to the Assistant Secretary for Electricity the same authority with respect to WAPA. By Redelegation Order No. 00–002.10–5, effective July 8, 2020, the Assistant Secretary for Electricity redelegated to WAPA's Administrator the same authority with respect to WAPA. However, based upon the governing terms of the existing BCP Electric Service Contract, the Assistant Secretary for Electricity will approve the FY 2022 base charge and rates for BCP electric service. This rate action is issued under the Redelegation Orders and DOE's procedures for public participation in rate adjustments set forth at 10 CFR parts 903 and 904.[3] The delegations and redelegations not affirmatively rescinded remain valid.

Availability of Information

All studies, comments, letters, memoranda, and other documents DSW initiates or uses to develop the proposed base charge and rates are available for inspection and copying at the Desert Southwest Customer Service Regional Office, Western Area Power Administration located at 615 South 43rd Avenue, Phoenix, Arizona 85009. Many of these documents and supporting information are also available on WAPA's website at *https://www.wapa.gov/regions/DSW/Rates/Pages/boulder-canyon-rates.aspx*.

Ratemaking Procedure Requirements

Environmental Compliance

WAPA is in the process of determining whether an environmental assessment or an environmental impact statement should be prepared or if this action can be categorically excluded from those requirements.[4]

[3] 50 FR 37835 (Sept. 18, 1985) and 84 FR 5347 (Feb. 21, 2019).

[4] In compliance with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500–1508), and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on March 26, 2021, by Tracey A. LeBeau, Administrator (Interim), Western Area Power Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on April 12, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–07702 Filed 4–14–21; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2021–0240 FRL–10022–34–OAR]

Technical Documentation for the Temperature Binning Framework

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of document availability and request for comments.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period for the draft document titled, ''Technical Documentation for the Temperature Binning Framework'' (EPA 430–R–21–004). This document provides technical documentation of a framework for analyzing the sector-specific impacts of climate change under different levels of warming. This approach serves as an alternative or complement to traditional scenario-based approaches in order to improve communication of results, comparability between studies, and flexibility to facilitate scenario analysis. The draft technical documentation will also be subject to external peer review. Prior to finalizing the draft document, EPA intends to carefully consider all comments received from the public and from external peer reviewers. This draft document is not final as described in EPA's information quality guidelines and does not represent and should not be construed to represent Agency policy or views. The draft document is available via the internet on EPA's web page at *https://www.epa.gov/cira/temperature-binning-framework.*

DATES: To ensure your comments are considered for the final version of the document, please submit your comments by May 17, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2021–0240, to the Federal Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. Do not submit electronically any information you consider to be Confidential Business Information (CBI). EPA may publish any comment received to its public docket, submitted to the Federal Portal, or sent via email. For additional submission methods, the full EPA public comment policy, information about CBI, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Mr. Jeremy Martinich, Environmental Protection Agency, Office of Air and Radiation, Office of Atmospheric Programs, Climate Change Division, (202) 343–9871, *cira@epa.gov.*

SUPPLEMENTARY INFORMATION: Characterizing the future risks of climate change is a key goal of climate impacts analysis. Temperature binning provides a framework for analyzing sector-specific impacts by degree of warming as an alternative or complement to traditional scenario-based approaches. This framework aims to improve communication of results, comparability between studies, flexibility to facilitate scenario analysis, and evaluation of important sources of uncertainty. This technical documentation describes the design, structure, and scientific basis of this framework, including how impact modeling projections for a number of sectors have been built into the framework. Designing analyses with relational temperature-impact functions for a given sector can improve comparability between analyses, yield results in a framework that is more intuitive for communications purposes, and be used to inform capabilities to

flexibly estimate impacts by sector for any desired scenario.

Paul Gunning,

Director, Climate Change Division.

[FR Doc. 2021–07670 Filed 4–14–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2015–0765; FRL–10021–18–ORD]

Board of Scientific Counselors (BOSC) Homeland Security Subcommittee Meeting—May 2021

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public meeting.

SUMMARY: The Environmental Protection Agency (EPA), Office of Research and Development (ORD), gives notice of a series of virtual meetings of the Board of Scientific Counselors (BOSC) Homeland Security (HS) Subcommittee to review progress on implementation of the Homeland Security Strategic Research Action Plan (StRAP).

DATES:

1. The initial meeting will be held over five days via videoconference:

a. Monday, May 17, 2021, from 12 p.m. to 5 p.m. (EDT);

b. Tuesday, May 18, 2021, from 12 p.m. to 5 p.m. (EDT);

c. Wednesday, May 19, 2021, from 12 p.m. to 5 p.m. (EDT);

d. Thursday, May 20, 2021, from 12 p.m. to 5 p.m. (EDT); and

e. Friday, May 21, 2021, from 12 p.m. to 5 p.m. (EDT).

Attendees must register by May 16, 2021.

2. A BOSC deliberation will be held on June 3, 2021, from 2 p.m. to 5 p.m. (EDT).

Attendees must register by June 2, 2021.

3. A final summary teleconference will be held on June 17, 2021, from 11 a.m. to 2 p.m. (EDT). Attendees must register by June 16, 2021.

Meeting times are subject to change. This series of meetings are open to the public. Comments must be received by May 16, 2021, to be considered by the subcommittee. Requests for the draft agenda or making a presentation at the meeting will be accepted until May 16, 2021.

ADDRESSES: Instructions on how to connect to the videoconference will be provided upon registration at *https://epa-bosc-homeland-security-subcommittee-mtg-2021.eventbrite.com.*

Submit your comments to Docket ID No. EPA–HQ–ORD–2015–0765 by one of the following methods:

- *www.regulations.gov:* Follow the online instructions for submitting comments.
- *Note:* comments submitted to the *www.regulations.gov* website are anonymous unless identifying information is included in the body of the comment.
- *Email:* Send comments by electronic mail (email) to: *ORD.Docket@epa.gov,* Attention Docket ID No. EPA–HQ–ORD–2015–0765.
- *Note:* comments submitted via email are not anonymous. The sender's email will be included in the body of the comment and placed in the public docket which is made available on the internet.

Instructions: All comments received, including any personal information provided, will be included in the public docket without change and may be made available online at *www.regulations.gov.* Information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute will not be included in the public docket, and should not be submitted through *www.regulations.gov* or email. For additional information about the EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/dockets.*

Public Docket: Publicly available docket materials may be accessed *Online* at *www.regulations.gov.*

Copyrighted materials in the docket are only available via hard copy. The telephone number for the ORD Docket Center is (202) 566–1752.

FOR FURTHER INFORMATION CONTACT: The Designated Federal Officer (DFO), Tom Tracy, via phone/voicemail at: (202) 564–6518; or via email at: *tracy.tom@epa.gov.*

Any member of the public interested in receiving a draft agenda, attending the meeting, or making a presentation at the meeting should contact Tom Tracy no later than May 16, 2021.

SUPPLEMENTARY INFORMATION: The Board of Scientific Counselors (BOSC) is a federal advisory committee that provides advice and recommendations to EPA's Office of Research and Development on technical and management issues of its research programs. The meeting agenda and materials will be posted to *https://www.epa.gov/bosc.*

Proposed agenda items for the meeting include, but are not limited to, the following: review progress on implementation of the Homeland Security Strategic Research Action Plan (StRAP).

Information on Services Available: For information on translation services, access, or services for individuals with disabilities, please contact Tom Tracy at (202) 564–6518 or *tracy.tom@epa.gov.* To request accommodation of a disability, please contact Tom Tracy at least ten days prior to the meeting to give the EPA adequate time to process your request.

Authority: Pub. L. 92–463, 1, Oct. 6, 1972, 86 Stat. 770.

Mary Ross,

Director, Office of Science Advisor, Policy and Engagement.

[FR Doc. 2021–07671 Filed 4–14–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1215; FRS 20901]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the

PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 14, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1215.

Title: Use of Spectrum Bands Above 24 GHz for Mobile Radio Services.

Form Number: N/A.

Type of Review: Revision of an existing collection.

Respondents: Business or other for-profit, not-for-profit institutions, and state, local and tribal government.

Number of Respondents: 1,670 respondents; 1,670 responses.

Estimated Time per Response: .5–10 hours.

Frequency of Response: On occasion reporting requirement; third party disclosure requirement; upon commencement of service, or within 3 years of effective date of rules; and at end of license term, or 2024 for incumbent licensees.

Obligation to Respond: Statutory authority for this collection are contained in sections 1, 2, 3, 4, 5, 7, 10, 201, 225, 227, 301, 302, 302a, 303, 304, 307, 309, 310, 316, 319, 332, and 336 of the Communications Act of 1934, 47 U.S.C. 151, 152, 153, 154, 155, 157, 160, 201, 225, 227, 301, 302, 302a, 303, 304, 307, 309, 310, 316, 319, 332, 336, Section 706 of the Telecommunications Act of 1996, as amended, 47 U.S.C. 1302.

Total Annual Burden: 790 hours.

Annual Cost Burden: $581,250.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: On November 19, 2020, the Commission released a Report and Order, FCC 20–159, in IB Docket No. 18–314, titled, ''Further Streamlining Part 25 Rules Governing Satellite Services.'' In this Report and Order, among other rule changes, the Commission adopted an optional, extended build-out period for earth station licensees. The optional build-out period increases the allowable time for an earth station to be brought into operation from within one year after licensing, to within: Up to five years and six months for earth stations operating with geostationary satellites; or, up to six years and six months for earth stations operating with non-geostationary satellites. As a companion provision to this new build-out period option, the Commission adopted a requirement for earth station licensees subject to 47 CFR 25.136 to re-coordinate with licensees of Upper Microwave Flexible Use Service (UMFUS) stations if the earth station is brought into operation later than one year after the date of the license grant. The earth station licensee must complete re-coordination within one year before its commencement of operation. The re-coordination should account for any demographic or geographic changes as well as changes to the earth station equipment or configuration. A re-coordination notice must also be filed with the Commission before commencement of earth station operations.

This information collection is used by UMFUS licensees to provide accurate information on the earth station operations notwithstanding the substantially longer earth station build-out period that was adopted. The collection also counterbalances the potential chilling of some UMFUS developments that might otherwise result from the extended earth station build-out periods, and thereby serves as an important check on potential warehousing. Without such information, the Commission would not be able to regulate the shared use of radio frequencies among earth stations and UMFUS stations in the public interest, in accordance with the Communications Act of 1934, as amended.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–07737 Filed 4–14–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0228; FRS 20905]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 14, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0228.

Title: Section 80.59, Compulsory Ship Inspections and Ship Inspection Certificates, FCC Forms 806, 824, 827 and 829.

Form Numbers: FCC Forms 806, 824, 827 and 829.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 2,438 respondents; 2,438 responses.

Estimated Time per Response: 0.084 hours (5 minutes)—4 hours per response.

Frequency of Response: On occasion, annual and every five-year reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation To Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 4, 303, 309, 332 and 362 of the Communications Act of 1934, as amended.

Total Annual Burden: 10,333 hours.

Total Annual Cost: No cost.

Privacy Impact Assessment: No impact(s).

Needs and Uses: The requirements contained in 47 CFR 80.59 of the Commission's rules are necessary to implement the provisions of section 362(b) of the Communications Act of 934, as amended, which require the Commission to inspect the radio installation of large cargo ships and certain passenger ships at least once a year to ensure that the radio installation is in compliance with the requirements of the Communications Act.

Further, section 80.59(d) states that the Commission may, upon a finding that the public interest would be served, grant a waiver of the annual inspection required by section 362(b) of the Communications Act of 1934, for a period of not more than 90 days for the sole purpose of enabling the United States vessel to complete its voyage and proceed to a port in the United States where an inspection can be held. An information application must be submitted by the ship's owner, operator or authorized agent. The application must be submitted to the Commission's District Director or Resident Agent in charge of the FCC office nearest the port of arrival at least three days before the ship's arrival. The application must provide specific information that is in rule section 80.59.

Additionally, the Communications Act requires the inspection of small passenger ships at least once every five years.

The Safety Convention (to which the United States is a signatory) also requires an annual inspection.

The Commission allows FCC-licensed technicians to conduct these inspections. FCC-licensed technicians certify that the ship has passed an inspection and issue a safety certificate. These safety certificates, FCC Forms 806, 824, 827 and 829 indicate that the vessel complies with the Communications Act of 1934, as amended and the Safety Convention. These technicians are required to provide a summary of the results of the inspection in the ship's log that the inspection was satisfactory.

Inspection certificates issued in accordance with the Safety Convention must be posted in a prominent and accessible place on the ship (third party disclosure requirement).

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–07738 Filed 4–14–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1113; FRS 20907]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 14, 2021. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1113.

Title: Election Whether to Participate in the Wireless Emergency Alert System.

Form No.: N/A.

Type of Review: Extension of a currently-approved collection.

Respondents: Business or other for-profit.

Number of Respondents and Responses: 1,253 respondents; 5,012 responses.

Estimated Time per Response: 0.5 (30 minutes)–12 hours.

Frequency of Response: On occasion reporting requirement, recordkeeping requirement and third party disclosure requirements.

Obligation to Respond: Mandatory and Voluntary. Statutory authority for this information collection is contained in 47 U.S.C. 151, 154(i), 154(j), 154(o), 218, 219, 230, 256, 302(a), 303(f), 303(g), 303(j), 303(r), 403, 621(b)(3), and 621(d).

Total Annual Burden: 28,820 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: This Commission is requesting an extension of a currently approved information collection from the Office of Management and Budget (OMB) in order to obtain the three-year approval after this 60-day comment period. It includes the collection of the following information from Commercial Mobile Service (CMS) providers: (1) Enhanced notice to consumers at time of sale (Enhanced Notice at Time of Sale); (2) disclosure as to degree of participation in wireless alerts (''in whole'' or ''in part'') (Notice of Election); (3) notice to current subscribers of non-participation in WEA (Notice to Current Subscribers); and (4) a collection to include voluntary information collection for a database that the Commission plans to create (Database Collection).

The Commission created WEA (previously known as the Commercial Mobile Service Alert System) as required by Congress in the Warning

Alert and Response Network (WARN) Act and to satisfy the Commission's mandate to promote the safety of life and property through the use of wire and radio communication.

All these information collections involve the Wireless Emergency Alert (WEA) system, a mechanism under which CMS providers may elect to transmit emergency alerts to the public. OMB last granted these collection requests on August 1, 2018 (ICR Ref. No. 201804–3060–013).

Notice of Election

On August 7, 2008, the Commission released the Third Report and Order in PS Docket No. 07–287 (CMS Third Report and Order), FCC 08–184. The CMS Third Report and Order implemented provisions of the WARN Act, including a requirement that within 30 days of release of the CMS Third Report and Order, each CMS provider must file an election with the Commission indicating whether or not it intends to transmit emergency alerts as part of WEA. The Commission began accepting WEA election filings on or before September 8, 2008.

The Bureau has sought several extensions of this information collection. On January 30, 2018, the Commission adopted a WEA Second Report and Order and Second Order on Reconsideration in PS Docket Nos. 15–91 and 15–94, FCC 18–4 (WEA Second R&O). In this order, the Commission defines ''in whole'' or ''in part'' WEA participation, specifies the difference between these elections, and requires CMS providers to update their election status accordingly.

Enhanced Notice at Time of Sale

Section 10.240 of the Commission's rules already requires that CMS Providers participating in WEA ''in part'' provide notice to consumers that WEA may not be available on all devices or within the entire service area, as well as details about the availability of WEA service. As part of the WEA Second R&O, the Commission adopted enhanced disclosure requirements, requiring CMS Providers participating in WEA ''in part'' to disclose the extent to which enhanced geo-targeting is available on their network and devices at the point of sale and the benefits of enhanced geo-targeting at the point of sale. We believe these disclosures will allow consumers to make more informed choices about their ability to receive WEA Alert Messages that are relevant to them.

Notice to Current Subscribers

A CMS provider that elects not to transmit WEA Alert Messages, in part or in whole, shall provide clear and conspicuous notice, which takes into account the needs of persons with disabilities, to existing subscribers of its non-election or partial election to provide Alert messages by means of an announcement amending the existing subscriber's service agreement.

A CMS provider that elects not to transmit WEA Alert Messages, in part or in whole, shall use the notification language set forth in § 10.240 (c) or (d) respectively, except that the last line of the notice shall reference FCC Rule 47 CFR 10.250, rather than FCC Rule 47 CFR 10.240.

In the case of prepaid customers, if a mailing address is available, the CMS provider shall provide the required notification via U.S. mail. If no mailing address is available, the CMS provider shall use any reasonable method at its disposal to alert the customer to a change in the terms and conditions of service and directing the subscriber to a voice-based notification or to a website providing the required notification.

Database Collection

The Commission also seeks to extend OMB approval in connection with the Commission's creation of a WEA database to improve information transparency for emergency managers and the public regarding the extent to which WEA is available in their area. The Commission will request this information from CMS providers on a voluntary basis, including geographic area served and devices that are programmed, at point of sale, to transmit WEAs. We note that many participating CMS providers already provide information of this nature in their docketed filings. As discussed below, this database will remove a major roadblock to emergency managers' ability to conduct tests of the alerting system and enable individuals and emergency managers to identify the alert coverage area.

Since ensuring consumer notice and collecting information on the extent of CMS providers' participation is statutorily mandated, the Commission requests to extend approval of this collection by OMB so that the Commission may continue to meet its statutory obligation under the WARN Act.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2021–07732 Filed 4–14–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1162; FRS 20885]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 14, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1162.

Title: Closed Captioning of Video Programming Delivered Using Internet

Protocol, and Apparatus Closed Caption Requirements.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or Household, Businesses or other for-profit, Not-for-profit institutions, State, local, or tribal government, Federal Government.

Number of Respondents and Responses: 1,172 respondents; 3,341 responses.

Estimated Time per Response: 0.084–10 hours.

Frequency of Response: One time and on occasion reporting requirements; Recordkeeping requirement; Third party disclosure requirement.

Obligation to Respond: Mandatory; Required to obtain or retain benefits. The statutory authority for this collection is contained in the Twenty-First Century Communications and Video Accessibility Act of 2010, Public Law 111–260, 124 Stat. 2751, and Sections 4(i), 4(j), 303, 330(b), 713, and 716 of the Communications Act of 1934, as amended (the Act), 47 U.S.C. 154(i), 154(j), 303, 330(b), 613, and 617.

Total Annual Burden: 9,197 hours.

Total Annual Cost: $95,700.

Privacy Act Impact Assessment: The FCC completed a Privacy Impact Assessment (PIA) on June 28, 2007. It may be reviewed at *https://www.fcc.gov/general/privacy-act-information#pia.* The Commission is in the process of updating the PIA to incorporate various revisions to it as a result of revisions to the FCC's system of records notice (SORN).

Nature and Extent of Confidentiality: Confidentiality is an issue to the extent that individuals and households provide personally identifiable information, which is covered under the FCC's SORN, FCC/CGB–1, ''Informal Complaints, Inquiries and Requests for Dispute Assistance,'' which became effective on September 24, 2014. We note that parties filing petitions for exemption based on economic burden, requests for Commission determinations of technical feasibility and achievability, requests for purpose-based waivers, or responses to complaints alleging violations of the Commission's rules may seek confidential treatment of information they provide pursuant to the Commission's existing confidentiality rules. The Commission is not requesting that individuals who file complaints alleging violations of our rules (complainants) submit confidential information (*e.g.,* credit card numbers, social security numbers, or personal financial information) to us. We request that complainants submit their names, addresses, and other contact information, which enables us to process complaints. Any use of this information is covered under the routine uses listed in the Commission's SORN, FCC/CGB–1.

Needs and Uses: The Twenty-First Century Communications and Video Accessibility Act of 2010 (CVAA) directed the Commission to revise its regulations to mandate closed captioning on video programming delivered via internet Protocol (IP) that was published or exhibited on television with captions after the effective date of the regulations. Accordingly, the Commission requires video programming owners (VPOs) to send program files to video programming distributors and providers (hereinafter VPDs) with required captions, and it requires VPDs to enable the rendering or pass through of all required captions to the end user. The CVAA also directed the Commission to revise its regulations to mandate that all apparatus designed to receive, play back, or record video programming be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, except that apparatus that use a picture screen that is 13 inches or smaller and recording devices must comply only if doing so is achievable. These rules are codified at 47 CFR 79.4 and 79.100–79.104.

The information collection requirements consist of:

(a) Mechanism for information about video programming subject to the IP closed captioning requirements.

Pursuant to 47 CFR 79.4(c)(1)(ii) and (c)(2)(ii) of the Commission's rules, VPOs and VPDs must agree upon a mechanism to make information available to VPDs about video programming that becomes subject to the requirements of 47 CFR 79.4 on an ongoing basis. VPDs must make a good faith effort to identify video programming that must be captioned when delivered using IP using the agreed upon mechanism.

For example, VPOs and VPDs may agree on a mechanism whereby the VPOs provide captions or certifications that captions are not required, and update those certifications and provide captions when captions later become required. A VPD may rely in good faith on a certification by a VPO that the programming need not be captioned if: (1) The certification includes a clear and concise explanation of why captions are not required; and (2) the VPD is able to produce the certification to the Commission in the event of a complaint. VPOs may provide certifications for specific programming or a more general certification, for example, for all programming covered by a particular contract.

VPDs may seek Commission determinations that other proposed mechanisms provide adequate information for them to rely on in good faith by filing an informal request and providing sufficient information for the Commission to make such determinations.

(b) Contact information for the receipt and handling of written closed captioning complaints.

Pursuant to 47 CFR 79.4(c)(2)(iii), VPDs must make their contact information available to end users for the receipt and handling of written IP closed captioning complaints. The required contact information includes the name of a person with primary responsibility for IP captioning issues and who can ensure compliance with these rules, as well as the person's title or office, telephone number, fax number, postal mailing address, and email address. VPDs must keep this information current and update it within 10 business days of any change. The Commission expects that such contact information will be prominently displayed in a way that it is accessible to all end users. A general notice on the VPD's website with such contact information, if provided, must be provided in a location that is conspicuous to viewers.

(c) Petitions for exemption based on economic burden.

Pursuant to 47 CFR 79.4(d), a VPO or VPD may petition the Commission for a full or partial exemption from the closed captioning requirements for IP-delivered video programming based upon a showing that they would be economically burdensome. Petitions for exemption must be supported with sufficient evidence to demonstrate economic burden (significant difficulty or expense). The Commission will consider four specific factors when determining economic burden and any other factors the petitioner deems relevant, along with any available alternatives that might constitute a reasonable substitute for the closed captioning requirements. The Commission will evaluate economic burden with regard to the individual outlet. Petitions and subsequent pleadings must be filed electronically.

The Commission will place such petitions on public notice. Comments or oppositions to the petition may be filed electronically within 30 days after release of the public notice of the petition, and must include a

certification that the petitioner was served with a copy. The petitioner may reply to any comments or oppositions filed within 20 days after the close of the period for filing comments or oppositions, and replies must include a certification that the commenting or opposing party was served with a copy. Upon a finding of good cause, the Commission may lengthen or shorten any comment period and waive or establish other procedural requirements. Petitions and responsive pleadings must include a detailed, full showing, supported by affidavit, of any facts or considerations relied on.

(d) Complaints alleging violations of the closed captioning rules for IP-delivered video programming.

Pursuant to 47 CFR 79.4(e), a written complaint alleging a violation of the closed captioning rules for IP-delivered video programming may be filed with the Commission or with the VPD responsible for enabling the rendering or pass through of the closed captions for the video programming. Complaints must be filed within 60 days after the date the complainant experienced a problem with captioning. Complaints should (but are not required to) include certain information.

If the complaint is filed first with the VPD, the VPD must respond in writing to the complainant within 30 days after receipt of a closed captioning complaint. If a VPD fails to respond timely, or the response does not satisfy the consumer, the complainant may re-file the complaint with the Commission within 30 days after the time allotted for the VPD to respond. If a consumer re-files the complaint with the Commission (after filing with the VPD) and the complaint satisfies the requirements, the Commission will forward the complaint to the named VPD, as well as to any other VPD and/or VPO that Commission staff determines may be involved, who then must respond in writing to the Commission and the complainant within 30 days after receipt of the complaint from the Commission.

If the complaint is filed first with the Commission and the complaint satisfies the requirements, the Commission will forward the complaint to the named VPD and/or VPO, and to any other VPD and/or VPO that Commission staff determine may be involved, who must respond in writing to the Commission and the complainant within 30 days after receipt of the complaint from the Commission. In response to a complaint, a VPD and/or VPO must provide the Commission with sufficient records and documentation. The Commission will review all relevant information provided by the complainant and the subject VPDs and/or VPOs, as well as any additional information the Commission deems relevant from its files or public sources. The Commission may request additional information from any relevant entities when, in the estimation of Commission staff, such information is needed to investigate the complaint or adjudicate potential violation(s) of Commission rules. When the Commission requests additional information, parties to which such requests are addressed must provide the requested information in the manner and within the time period the Commission specifies.

(e) Requests for Commission determination of technical feasibility of apparatus closed caption requirements.

Pursuant to 47 CFR 79.103(a), as of January 1, 2014, all digital apparatus designed to receive or play back video programming that uses a picture screen of any size must be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, if technically feasible. If new apparatus or classes of apparatus for viewing video programming emerge on which it would not be technically feasible to include closed captioning, parties may raise that argument as a defense to a complaint or, alternatively, file a request under 47 CFR 1.41 for a Commission determination of technical feasibility before manufacturing or importing the product.

(f) Requests for Commission determination of achievability of apparatus closed caption requirements.

Pursuant to 47 CFR 79.103(a), as of January 1, 2014, all digital apparatus designed to receive or play back video programming that use a picture screen less than 13 inches in size must be equipped with built-in closed caption decoder circuitry or capability designed to display closed-captioned video programming, only if doing so is achievable. In addition, pursuant to 47 CFR 79.104(a), as of January 1, 2014, all apparatus designed to record video programming must enable the rendering or the pass through of closed captions such that viewers are able to activate and de-activate the closed captions as the video programming is played back, only if doing so is achievable.

Manufacturers of such apparatus may petition the Commission, pursuant to 47 CFR 1.41, for a full or partial exemption from the closed captioning requirements before manufacturing or importing the apparatus or may assert as a response to a complaint that these requirements, in full or in part, are not achievable. Pursuant to 47 CFR 79.103(b)(3), such a petition or response must be supported with sufficient evidence to demonstrate that compliance is not achievable (meaning with reasonable effort or expense) and the Commission will consider four specific factors when making such determinations.

(g) Petitions for purpose-based waivers of apparatus closed caption requirements.

Manufacturers seeking certainty prior to the sale of a device may petition the Commission, pursuant to 47 CFR 79.103(b)(4), for a full or partial waiver of the closed captioning requirements based on one of the following provisions:

(i) The apparatus is primarily designed for activities other than receiving or playing back video programming transmitted simultaneously with sound; or

(ii) The apparatus is designed for multiple purposes, capable of receiving or playing back video programming transmitted simultaneously with sound but whose essential utility is derived from other purposes.

(h) Complaints alleging violations of the apparatus closed caption requirements.

Consumers may file written complaints alleging violations of the Commission's rules, 47 CFR 79.101–79.104, requiring apparatus designed to receive, play back, or record video programming to be equipped with built-in closed caption decoder circuitry or capability designed to display closed captions. A written complaint filed with the Commission must be transmitted to the Consumer and Governmental Affairs Bureau through the Commission's online informal complaint filing system, U.S. Mail, overnight delivery, or facsimile. Such complaints should include certain information about the complainant and the alleged violation. The Commission may forward such complaints to the named manufacturer or provider, as well as to any other entity that Commission staff determines may be involved, and may request additional information from any relevant parties when, in the estimation of Commission staff, such information is needed to investigate the complaint or adjudicate potential violations of Commission rules.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2021–07736 Filed 4–14–21; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

TIME AND DATE: Tuesday, April 20, 2021 at 10:00 a.m. and its continuation at the conclusion of the open meeting on April 22, 2021.

PLACE: 1050 First Street NE, Washington, DC. (This meeting will be a virtual meeting.)

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Compliance matters pursuant to 52 U.S.C. 30109.

Matters relating to internal personnel decisions, or internal rules and practices.

Investigatory records compiled for law enforcement purposes and production would disclose investigative techniques.

Matters concerning participation in civil actions or proceedings or arbitration.

* * * * *

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Vicktoria J. Allen,

Acting Deputy Secretary of the Commission.

[FR Doc. 2021–07898 Filed 4–13–21; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm*. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington DC 20551–0001, not later than April 30, 2021.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23219. Comments can also be sent electronically to or *Comments.applications@rich.frb.org*:

1. *FVCBankcorp, through its subsidiary bank, FVCBank, both of Fairfax, Virginia*; to acquire voting shares of Atlantic Coast Mortgage, LLC, Fairfax, Virginia, and thereby engage in extending credit and servicing loans, and real estate and personal property appraising activities, pursuant to section 225. 28(b)(1) and (b)(2)(i) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, April 9, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–07682 Filed 4–14–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

Correction

In the **Federal Register** of March 30, 2021, FR Doc. 2021–06462, the notice ''Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies'' by the Federal Reserve Bank of Atlanta, *TC Bancshares, Inc., Thomasville, Georgia*; is corrected to read ''Formations of, Acquisitions by, and Mergers of Bank Holding Companies'', and that the company listed applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations, to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company. The comment period continues to end on April 28, 2021. Interested persons may continue to view the notice and submit comments as provided in 86 FR 16599 (March 30, 2021) no later than April 28, 2021.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2021–07726 Filed 4–14–21; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

Correction

In the **Federal Register** of March 31, 2021, FR Doc. 2021–06525, the notice ''Formations of, Acquisitions by, and Mergers of Savings and Loan Holding Companies'' by the Federal Reserve Bank of Atlanta, *Catalyst Bancorp, Inc., Opelousas, Louisiana;* is corrected to read ''Formations of, Acquisitions by, and Mergers of Bank Holding Companies'', and that the company listed applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations, to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company. The comment period continues to end on April 29, 2021. Interested persons may continue to view the notice and submit comments as provided in 86 FR 16727 (March 31, 2021) no later than April 29, 2021.

Board of Governors of the Federal Reserve System.

Ann Misback,

Secretary of the Board.

[FR Doc. 2021–07727 Filed 4–14–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0043; Docket No. 2021–0053; Sequence No. 6]

Information Collection; Delivery Schedules

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, DoD, GSA, and NASA invite the public to comment on a revision and renewal concerning delivery schedules. DoD, GSA, and NASA invite comments on: Whether the proposed collection of information is necessary for the proper performance of the functions of Federal Government acquisitions, including whether the information will have practical utility; the accuracy of the estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including the use of automated collection techniques or other forms of information technology. OMB has approved this information collection for use through November 30, 2021. DoD, GSA, and NASA propose that OMB extend its approval for use for three additional years beyond the current expiration date.

DATES: DoD, GSA, and NASA will consider all comments received by June 14, 2021.

ADDRESSES: DoD, GSA, and NASA invite interested persons to submit comments on this collection through *http://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

Instructions: All items submitted must cite OMB Control No. 9000–0043, Delivery Schedules. Comments received generally will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: Zenaida Delgado, Procurement Analyst, at telephone 202–969–7207, or *zenaida.delgado@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0043, Delivery Schedules.

B. Need and Uses

This clearance covers the information that offerors may submit to comply with the following Federal Acquisition Regulation (FAR) requirements:

- 52.211–8, Time of Delivery
- 52.211–9, Desired and Required Time of Delivery

Contracting officers may use one of these time of delivery clauses to set forth a required delivery schedule and to allow offerors to propose an alternative delivery schedule. Contracting officers use this information to ensure supplies or services are obtained in a timely manner.

C. Annual Burden

Respondents: 1,527.
Total Annual Responses: 1,527.
Total Burden Hours: 763.5.
Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.* Please cite OMB Control No. 9000–0043, Delivery Schedules.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2021–07739 Filed 4–14–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0076; Docket No. 2021–0053; Sequence No. 2]

Submission for OMB Review; Novation and Change-of-Name Agreements

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division has submitted to the Office of Management and Budget (OMB) a request to review and approve a revision and extension of a previously approved information collection requirements regarding improper business practices and personal conflicts of interest.

DATES: Submit comments on or before May 17, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. Additionally, submit a copy to GSA through *https://www.regulations.gov* and follow the instructions on the site. This website provides the ability to type short comments directly into the comment field or attach a file for lengthier comments.

Instructions: All items submitted must cite ''9000–0076, Novation and Change-of-Name Agreements.'' Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *https://www.regulations.gov* approximately two-to-three days after submission to verify posting. If there are difficulties submitting comments, contact the GSA Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Hawes, Procurement Analyst, at telephone 202–969–7386, or *jennifer.hawes@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. OMB Control Number, Title, and Any Associated Form(s)

9000–0076, Novation and Change-of-Name Agreements.

B. Need and Uses

This clearance covers the information that contractors must submit to comply with the following requirements in Federal Acquisition Regulation subpart 42.12:

- *42.1203(a), Written Request.* If a contractor wishes the Government to recognize a successor in interest to its

contracts or a name change, the contractor must submit a written request to the responsible contracting officer. The request is used to by the contracting officer to determine what additional supporting documentation should be submitted by the contractor and to determine what other contract administration offices should be notified of the contractor's request.

• *42.1204(e) and (f), Novation Agreement.* Pursuant to 42.1203(b)(1), upon request from the contracting officer, the contractor shall submit three signed copies of the proposed novation agreement, plus copies of the supporting documentation listed at 42.1204(e) and (f), as applicable. The documentation is used by the contracting officer to evaluate and, if appropriate, execute a proposed agreement for recognizing a third party as a successor in interest.

• *42.1205(a), Change-of-Name Agreement.* Pursuant to 42.1203(b)(1), upon request from the contracting officer, the contractor shall submit three signed copies of the proposed change-of-name agreement, plus copies of the supporting documentation listed at 42.1205(a), as applicable. The documentation is used by the contracting officer to evaluate and, if appropriate, execute a proposed agreement for recognizing a contractor's name change.

C. Annual Burden

Respondents: 1,515.

Total Annual Responses: 1,515.

Total Burden Hours: 2,701.

D. Public Comment

A 60-day notice was published in the **Federal Register** at 86 FR 8017, on February 3, 2021. No comments were received.

Obtaining Copies: Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202–501–4755 or emailing *GSARegSec@gsa.gov.*

Please cite OMB Control No. 9000–0076, Novation and Change-of-Name Agreements.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2021–07691 Filed 4–14–21; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Evaluation of LifeSet (New Collection)

AGENCY: Office of Planning, Research, and Evaluation; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) is proposing a new information collection activity to assess the impact and implementation of LifeSet, a program that provides services and supports to young adults ages 17 to 21 with previous child welfare involvement. Data collection efforts will include accessing administrative data from the child welfare agency, program, and other private and governmental databases; surveys of young adults (participants and those receiving services as usual); interviews and focus groups with program and child welfare agency administrators and staff; interviews and focus groups with young adult program participants; and interviews with other program stakeholders.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *OPREinfocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed information collection activity is the first phase of a larger study that intends to assess the impact and implementation of LifeSet, a program that provides services and supports to young adults ages 17 to 21 with previous child welfare involvement. The program aims to support young adults in their transition from foster care to independent living in the areas of education, employment and earnings, housing and economic well-being, social support, well-being, health and safety, and criminal involvement. It focuses on helping young adults identify and achieve their goals while developing the skills necessary for independent living.

The impact study will assess the effects of young adults' participation in LifeSet on outcomes in the primary (*i.e.* confirmatory) domains of education and employment, housing stability, social support, and well-being. These outcomes have been identified by the implementing agency as the main areas they expect to target for positive program impacts. In addition, the impact study will explore the effects of participation in the secondary (*i.e.* exploratory) domains of mental health, criminal justice system contact, intimate partner violence, and economic well-being. The study will utilize a randomized controlled design. Information collection activities will take place over three years and will include collection of administrative data from the state child welfare agency, the program developer, the local program provider agencies, the National Student Clearinghouse, unemployment insurance and employer wage records, the National Directory of New Hires, the state homelessness management information system, the state department of corrections, the state juvenile justice commission, the state court probation services division, and the state department of human services division of family development, as well as survey interviews with program participants and young adults receiving services as usual.

The implementation study will collect information through phone calls and site visits to the participating program and child welfare agency. Information collection activities include interviews and focus groups with administrators and staff from the program developer, child welfare agency, and program providers.

This evaluation is part of a larger project to help ACF build the evidence base in child welfare through rigorous evaluation of programs, practices, and policies. The activities and products from this project will contribute to evidence building in child welfare and help to determine the effectiveness of a program for youth formerly in foster care on young adult outcomes.

Respondents: Program participants, young adults receiving services as usual, agency and program administrators and staff, other program stakeholders.

ANNUAL BURDEN ESTIMATES

Instrument	Respondents	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Avg. burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
Site Visit 1 Interview Guide for Administrators.	Child Welfare Agency Administrators Licensed LifeSet Experts. Provider Agency Administrators. LifeSet Developer Administrators.	22	1	1	22	7
Site Visit 2 Interview Guide for Administrators.	Child Welfare Agency Administrators Licensed LifeSet Experts. Provider Agency Administrators. LifeSet Developer Administrators.	22	1	1	22	7
Site Visit 2 Focus Group Guide for Staff.	LifeSet Specialists LifeSet Team Supervisors.	12	1	1.5	18	6
Baseline Youth Survey	Youth Formerly in Foster Care	600	1	0.6	360	120
Administrative data file	Agency and Program Staff	12	1	5	60	20

Estimated Total Annual Burden Hours: 160.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 677.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–07688 Filed 4–14–21; 8:45 am]

BILLING CODE 4184–25–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Leveraging Big Data Science to Elucidate the Mechanisms of HIV Activity and Interaction with Substance Use Disorder (R01, R21—Clinical Trials Not Allowed).

Date: May 18, 2021.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ipolia R. Ramadan, Ph.D., Scientific Review Officer, Office of Extramural Policy and Review, Division of Extramural Research, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 827–4471, *ramadanir@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 9, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07708 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be held as a virtual meeting and is open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of this will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: May 11, 2021.

Closed: 11:00 a.m. to 12:15 p.m.

Agenda: To review and evaluate grant applications.

Open: 12:45 p.m. to 4:30 p.m.

Agenda: Presentations and other business of the Council.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, Three White Flint North, RM 09D08, 11601 Landsdown Street, Bethesda, MD 20852, 301–443–6480, *sweiss@nida.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when

applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 9, 2021.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07712 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Human Genome Research Institute Special Emphasis Panel; Gabriella Miller Kids First and INCLUDE SEP.

Date: May 7, 2021.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: National Human Genome Research Institute, National Institutes of Health, Barbara J. Thomas, Ph.D., Scientific Review Officer, Scientific Review Branch, 6700B Rockledge Drive, Suite 3100, Bethesda, MD 20892–6908, 301–402–8837, *barbara.thomas@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: April 9, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07711 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–2: NCI Clinical and Translational Cancer Research.

Date: June 3–4, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Ombretta Salvucci, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W264, Rockville, Maryland 20850, 240–276–7286, *salvucco@mail.nih.gov.*

Name of Committee: National Cancer Institute Initial Review Group; Subcommittee F—Institutional Training and Education.

Date: June 8, 2021.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240–276–6368, *Stoicaa2@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Program Project V (P01).

Date: June 10–11, 2021.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W240, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Hasan Siddiqui, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W240, Rockville, Maryland 20850, 240–276–5122, *hasan.siddiqui@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–9: NCI Clinical and Translational Cancer Research.

Date: June 24, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Clifford W. Schweinfest, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W108, Rockville, Maryland 20850, 240–276–6343, *schweinfestcw@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Research Specialist Award (R50).

Date: June 24–25, 2021.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, 240–276–6372, *zouzhiq@mail.nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; Social and Behavioral Intervention Research to Address Modifiable Risk Factors for Cancer in Rural Populations (R01).

Date: June 25, 2021.

Time: 10:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850, (Telephone Conference Call).

Contact Person: Mukesh Kumar, Ph.D., Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W618, Rockville, Maryland 20850, 240–276–6611, *mukesh.kumar3@nih.gov.*

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Pathway to Independence Award for Outstanding Early Stage Postdoctoral Researchers (K99/R00).

Date: June 30, 2021.
Time: 10:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W238, Rockville, Maryland 20850, (Telephone Conference Call).
Contact Person: Byeong-Chel Lee, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W238, Rockville, Maryland 20850, 240–276–7755, *byeong-chel.lee@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; NCI Research Specialist Award.
Date: July 1, 2021.
Time: 10:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, (Telephone Conference Call)
Contact Person: Zhiqiang Zou, M.D., Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W242, Rockville, Maryland 20850, 240–276–6372, *zouzhiq@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Training Grant SEP.
Date: July 1, 2021.
Time: 1:00 p.m. to 3:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, (Telephone Conference Call)
Contact Person: Adriana Stoica, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W234, Rockville, Maryland 20850, 240–276–6368, *Stoicaa2@mail.nih.gov*

Name of Committee: National Cancer Institute Special Emphasis Panel; SEP–6: NCI Clinical and Translational Cancer Research.
Date: July 9, 2021.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Cancer Institute at Shady Grove, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, (Telephone Conference Call)
Contact Person: Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, Maryland 20850, 240–276–5856 *nadeem.khan@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: April 12, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07745 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be held as a virtual meeting and is open to the public as indicated below. Individuals who plan to view the virtual meeting and need special assistance or other reasonable accommodations to view the meeting, should notify the Contact Person listed below in advance of the meeting. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health and Health Disparities.
Date: May 24, 2021.
Closed: 1:00 p.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Name of Committee: National Advisory Council on Minority Health and Health Disparities.
Date: May 25, 2021.
Open: 11:00 a.m. to 4:00 p.m.
Agenda: Opening Remarks, Administrative Matters, Director's Report, Presentations, and Other Business of the Council.
Place: National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).
Contact Person: Thomas M. Vollberg, Sr., Ph.D., Director, Office of Extramural Research Administration, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Boulevard, Suite 800, Bethesda, Maryland 20892–5465, 301–402–1366, *Thomas.Vollberg@nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: NIMHD: *https://www.nimhd.nih.gov/about/advisory-council/*, where an agenda and any additional information for the meeting will be posted when available.

Dated: April 9, 2021.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07710 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Dawn Taylor-Mulneix at 301–767–5189 or d*awn.taylor-mulneix@nih.gov*. Licensing information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished information related to the invention.

SUPPLEMENTARY INFORMATION: Technology description follows:

Human Monoclonal and Bispecific Antibodies Targeting SARS–CoV–2 Coronavirus

Description of Technology

SARS–CoV–2 is a virus of the Coronavirus family that has emerged as a major public health concern. The first cases of SARS–CoV–2 were reported in China and rapidly spread worldwide leading to a global pandemic. The highest morbidity and mortality have been reported in the elderly and immunocompromised. Antibody therapeutics have great importance for advanced cases of SARS–CoV–2 where a vaccine would not be effective and may be more effective than a vaccine in certain high-risk populations.

Scientists at NIAID have developed recombinant monoclonal antibodies that are effective *in vitro* and *in vivo* at neutralizing SARS–CoV–2. Based on whether they are mono-specific or bi-specific and where they bind to the SARS–CoV–2 virus, these antibodies can be subdivided into four groups that target (A) the receptor-binding-domain (RBD) of the SARS–COV–2 spike protein, (B) the N-terminal domain (NTD) of the SARS–COV–2 spike protein, (C) dual locations on the RBD, or (D) both the RBD and NTD. Crucially, these antibodies effectively neutralize the emerging B.1.1.7 and B.1.351 SARS–CoV–2 variants of concern.

These recombinant monoclonal antibodies can be used alone, in combination, or with other therapeutics for the treatment of SARS–COV–2. In addition to their potential as therapeutics, these antibodies against SARS–CoV–2 can be used as prophylactics and in assay development. They can contribute to the surveillance, diagnosis, and prevention of SARS–COV–2. Furthermore, the specific antibody sequences and targets will inform vaccine development and establishment of long-term immunity.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Prophylaxis or therapeutics against SARS–CoV–2.
- Diagnostics and surveillance of SARS–CoV–2.
- Vaccine research.

Competitive Advantages

- Potent neutralizing activity against SARS–CoV–2, including against B.1.1.7 and B.1.351 variants.
- Prophylactic usage against SARS–CoV–2 in normal or high-risk populations.
- Therapeutic treatment, alone or in combination, in patients with SARS–CoV–2 infection.
- Assay development for surveillance, diagnostic, and prevention measures.
- Identification of vaccine candidates which elicit protective antibodies against SARS–CoV–2 infections.

Development Stage

- Pre-clinical.

Inventors: Joshua Tan, Ph.D., Peter Crompton, M.D., Hyeseon Cho, Ph.D., Mary Peterson, Kristina Kay Gonzales-Wartz, Ph.D., all of NIAID.

Publications: Cho, Hyeseon, et al. ''Ultrapotent bispecific antibodies neutralize emerging SARS–CoV–2 variants.'' bioRxiv 2021.04.01.437942;

Intellectual Property: HHS Reference No. E–030–2021–0; US provisional application No. 63/127,077 filed on December 17, 2020.

Licensing Contact: To license this technology, please contact Dawn Taylor-Mulneix 301–767–5189 or *dawn.taylor-mulneix@nih.gov,* and reference E–030–2021–0.

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Dawn Taylor-Mulneix at 301–767–5189 or *dawn.taylor-mulneix@nih.gov*.

Dated: April 7, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021–07709 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Initial Review Group; Biobehavioral and Behavioral Sciences Subcommittee.

Date: June 28, 2021.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: NICHD Offices, 6710B Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Clay Mash, Ph.D., Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Drive, Rm. 2131A, Bethesda, MD 20892, (301) 496–6866, *mashc@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 12, 2021.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07735 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Instrumentation and Systems Development Study Section.

Date: June 17–18, 2021.

Time: 9:30 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kee Forbes, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5148, MSC 7806, Bethesda, MD 20892, 301–272–4865, *pyonkh2@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 12, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–07746 Filed 4–14–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS–2021–0016]

DHS Data Privacy and Integrity Advisory Committee

AGENCY: Privacy Office, Department of Homeland Security (DHS).

ACTION: Committee management; notice of Federal Advisory Committee meeting.

SUMMARY: The DHS Data Privacy and Integrity Advisory Committee will meet on Friday, May 14, 2021, via virtual conference. The meeting will be open to the public.

DATES: The DHS Data Privacy and Integrity Advisory Committee will meet on Friday, May 14, 2021, from 1:00 p.m. to 3:00 p.m. Please note that the virtual conference may end early if the Committee has completed its business.

ADDRESSES: The meeting will be held via a virtual forum (conference information will be posted on the Privacy Office website in advance of the meeting at *www.dhs.gov/privacy-advisory-committee*), or call (202) 343–1717, to obtain the information. For information on services for individuals with disabilities, or to request special assistance during the meeting, please contact Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, as soon as possible.

To facilitate public participation, we invite public comment on the issues to be considered by the Committee as listed in the **SUPPLEMENTARY INFORMATION** section below. A public comment period will be held during the meeting, and speakers are requested to limit their comments to three minutes. If you would like to address the Committee at the meeting, we request that you register in advance by contacting Nicole Sanchez at the address provided below. The names and affiliations of individuals who address the Committee will be included in the public record of the meeting. Please note that the public comment period may end before the time indicated, following the last call for comments. Advanced written comments or comments for the record, including from persons who wish to submit comments and who are unable to participate or speak at the meeting, should be sent to Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, by May 7, 2021. All submissions must include the Docket Number (DHS–2021–0016) and may be submitted by any *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email: PrivacyCommittee@hq.dhs.gov.* Include the Docket Number (DHS–2021–0016) in the subject line of the message.
- *Fax:* (202) 343–4010.
- *Mail:* Nicole Sanchez, Designated Federal Officer, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, 245 Murray Lane SW, Mail Stop 0655, Washington, DC 20528.

Instructions: All submissions must include the words ''Department of Homeland Security Data Privacy and Integrity Advisory Committee'' and the Docket Number (DHS–2021–0016). Comments received will be posted without alteration at *http://www.regulations.gov,* including any personal information provided.

The DHS Privacy Office encourages you to register for the meeting in advance by contacting Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, at *PrivacyCommittee@hq.dhs.gov.* Advance registration is voluntary. The Privacy Act Statement below explains how DHS uses the registration information you may provide and how you may access or correct information retained by DHS, if any.

Docket: For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Advisory Committee, go to *http://www.regulations.gov* and search for docket number DHS–2021–0016.

FOR FURTHER INFORMATION CONTACT: Nicole Sanchez, Designated Federal Officer, DHS Data Privacy and Integrity Advisory Committee, Department of Homeland Security, 245 Murray Lane SW, Mail Stop 0655, Washington, DC 20528, by telephone (202) 343–1717, by fax (202) 343–4010, or by email to *PrivacyCommittee@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Title 5, U.S.C. The DHS Data Privacy and Integrity Advisory Committee provides advice at the request of the Secretary of Homeland Security and the DHS Chief Privacy Officer on programmatic, policy, operational, administrative, and technological issues within DHS that relate to personally identifiable information, as well as data integrity and other privacy-related matters. The Committee was established by the Secretary of Homeland Security under the authority of 6 U.S.C. 451.

Proposed Agenda

During the meeting, the Committee will provide updates on its response to the latest taskings from the DHS Chief Privacy Officer. The Tasking Memorandum is available at: *https://www.dhs.gov/publication/dpiac-meeting-october-27-2020.* If you wish to submit written comments, you may do so in advance of the meeting by forwarding them to the Committee at the locations listed under **ADDRESSES**. The final agenda will be posted on or before May 7, 2021, on the Committee's website at *www.dhs.gov/dhs-data-privacy-and-integrity-advisory-committee-meeting-information.*

Privacy Act Statement: DHS's Use of Your Information

Authority: DHS requests that you voluntarily submit this information under its following authorities: The Federal Records Act, 44 U.S.C. 3101; the FACA, 5 U.S.C. appendix; and the Privacy Act of 1974, 5 U.S.C. 552a.

Principal Purposes: When you register to attend a DHS Data Privacy and Integrity Advisory Committee meeting, DHS collects your name, contact information, and the organization you represent, if any. We use this information to contact you for purposes related to the meeting, such as to confirm your registration, to advise you of any changes in the meeting, or to assure that we have sufficient materials to distribute to all attendees. We may also use the information you provide for public record purposes such as posting

publicly available transcripts and meeting minutes.

Routine Uses and Sharing: In general, DHS will not use the information you provide for any purpose other than the Principal Purposes, and will not share this information within or outside the agency. In certain circumstances, DHS may share this information on a case-by-case basis as required by law or as necessary for a specific purpose, as described in the DHS/ALL–002 Mailing and Other Lists System of Records Notice (November 25, 2008, 73 FR 71659).

Effects of Not Providing Information: You may choose not to provide the requested information or to provide only some of the information DHS requests. If you choose not to provide some or all of the requested information, DHS may not be able to contact you for purposes related to the meeting.

Accessing and Correcting Information: If you are unable to access or correct this information by using the method that you originally used to submit it, you may direct your request in writing to the DHS Deputy Chief FOIA Officer at *foia@hq.dhs.gov.* Additional instructions are available at *http://www.dhs.gov/foia* and in the DHS/ALL–002 Mailing and Other Lists System of Records referenced above.

Lynn Parker Dupree,

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2021–07681 Filed 4–14–21; 8:45 am]

BILLING CODE 9110–9L–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[212 LLUT912000 L13140000.PP0000]

Notice of Public Meeting, Utah Resource Advisory Council, Utah

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act, the Federal Advisory Committee Act, and the Federal Lands Recreation Enhancement Act, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Utah Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Utah RAC will hold an online meeting on May 25, 2021, from 8 a.m. to 4:30 p.m. The meeting is open to the public.

ADDRESSES: The agenda and meeting registration information will be posted on the Utah RAC web page 30 days before the meeting at *https://www.blm.gov/get-involved/resource-advisory-council/near-you/utah/RAC.* Written comments to address the Utah RAC may be sent to the BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101, or via email to *BLM_UT_External_Affairs@blm.gov* with the subject line ''Utah RAC Meeting.''

FOR FURTHER INFORMATION CONTACT: Lola Bird, Public Affairs Specialist, BLM Utah State Office, 440 West 200 South, Suite 500, Salt Lake City, Utah 84101; phone (801) 539–4033; or email *lbird@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to leave a message or question for the above individual. The FRS is available 24 hours a day, 7 days a week. Replies are provided during normal business hours.

SUPPLEMENTARY INFORMATION: The Utah RAC provides recommendations to the Secretary of the Interior, through the BLM, on a variety of public lands issues. Agenda topics will include: BLM Utah priorities, renewable energy, Great American Outdoors Act update, recreation strategy, recreation dispersed camping, recreation High Desert trail (from Washington County to Tooele), recreation annual passes around the state, back country air strips in resource management plans, recreation management by the BLM and State of Utah in Red Cliffs Zone 6, Modified Cedar City Field Office Recreation Site Business Plan, and other issues as appropriate. The Utah RAC will offer a 30-minute public comment period. Depending on the number of people wishing to comment and the time available, the amount of time for individual oral comments may be limited. Written comments may also be sent to the BLM Utah State Office at the address listed in the **ADDRESSES** section of this notice. All comments received will be provided to the Utah RAC.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Detailed meeting minutes for the Utah RAC meeting will be maintained in the BLM Utah State Office and will be available for public inspection and reproduction during regular business hours within 90 days following the meeting. Minutes will also be posted to the Utah RAC web page.

Authority: 43 CFR 1784.4–2.

Abbie Jossie,

Acting State Director.

[FR Doc. 2021–07724 Filed 4–14–21; 8:45 am]

BILLING CODE 4310–DQ–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031673; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Colorado Bureau of Investigation, Arvada, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Colorado Bureau of Investigation has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is no cultural affiliation between the human remains and any present-day Indian Tribes or Native Hawaiian organizations. Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Colorado Bureau of Investigation. If no additional requestors come forward, transfer of control of the human remains to the Indian Tribes or Native Hawaiian organizations stated in this notice may proceed.

DATES: Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to the Colorado Bureau of Investigation at the address in this notice by May 17, 2021.

ADDRESSES: Greg Hake, Colorado Bureau of Investigation, 6000 W 54th Avenue, Arvada, CO 80002, telephone (303) 463–7050, email *greg.hake@state.co.us.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Colorado Bureau of Investigation, Arvada, CO. The human remains were

removed from unknown location(s) in Colorado.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3) and 43 CFR 10.11(d). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Colorado Bureau of Investigation professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Arapaho Tribe of the Wind River Reservation, Wyoming; Cheyenne and Arapahoe Tribes, Oklahoma (previously listed as Cheyenne-Arapaho Tribes of Oklahoma); Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Comanche Nation, Oklahoma; Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota; Crow Tribe of Montana; Eastern Shoshone Tribe of the Wind River Reservation, Wyoming (previously listed as Shoshone Tribe of the Wind River Reservation, Wyoming); Fort Sill Apache Tribe of Oklahoma; Hopi Tribe of Arizona; Jicarilla Apache Nation, New Mexico; Kewa Pueblo, New Mexico (previously listed as Pueblo of Santo Domingo); Kiowa Indian Tribe of Oklahoma; Mescalero Apache Tribe of the Mescalero Reservation, New Mexico; Navajo Nation, Arizona, New Mexico & Utah; Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana; Oglala Sioux Tribe (previously listed as Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota); Ohkay Owingeh, New Mexico (previously listed as Pueblo of San Juan); Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes (previously listed as Paiute Indian Tribe of Utah (Cedar City Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes)); Pawnee Nation of Oklahoma; Pueblo of Acoma, New Mexico; Pueblo of Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo of San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; San Juan Southern Paiute Tribe of Arizona; Shoshone-Bannock Tribes of the Fort Hall Reservation; Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado; Standing Rock Sioux Tribe of North & South Dakota; The Osage Nation (previously listed as Osage Tribe); Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota; Ute Indian Tribe of the Uintah & Ouray Reservation, Utah; Ute Mountain Ute Tribe (previously listed as Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah); Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma; Ysleta del Sur Pueblo (previously listed as Ysleta Del Sur Pueblo of Texas); and Zuni Tribe of the Zuni Reservation, New Mexico (hereafter referred to as ''The Invited and Consulted Tribes'').

History and Description of the Remains

More than 20 years ago, human remains representing, at minimum, three individuals were removed from unknown location(s) in Colorado. The human remains consist of a cranium, partial mandible, and partial left fibula. Based on analysis by Diane France of the Human Identification Laboratory of Colorado, the human remains are Native American. No known individuals were identified. No associated funerary objects are present.

Determinations Made by the Colorado Bureau of Investigation

Officials of the Colorado Bureau of Investigation have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice are Native American.
- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), a relationship of shared group identity cannot be reasonably traced between the Native American human remains and any present-day Indian Tribe.
- According to final judgments of the Indian Claims Commission or the Court of Federal Claims, the land from which the Native American human remains were removed is the aboriginal land of The Invited and Consulted Tribes.
- Treaties, Acts of Congress, or Executive Orders indicate that the land from which the Native American human remains were removed is the aboriginal land of The Invited and Consulted Tribes.
- Pursuant to 43 CFR 10.11(c)(1), the disposition of the human remains may be to The Invited and Consulted Tribes.

Additional Requestors and Disposition

Representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Greg Hake, Colorado Bureau of Investigation, 6000 W 54th Avenue, Arvada, CO 80002, telephone (303) 463–7050, email *greg.hake@state.co.us,* by May 17, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to the Invited and Consulted Tribes may proceed. The Southern Ute Tribe and Ute Mountain Ute Tribe have agreed to accept disposition.

The Colorado Bureau of Investigation is responsible for notifying The Invited and Consulted Tribes that this notice has been published.

Dated: April 6, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–07699 Filed 4–14–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031686; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Temple University, Philadelphia, PA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Temple University has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to Temple University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the

lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Temple University at the address in this notice by May 17, 2021.

ADDRESSES: Leslie Reeder-Myers, Temple University, 1115 Polett Walk, Gladfelter Hall Room 204, Philadelphia, PA 19122, telephone (215) 204–1418, email *leslie.reeder-myers@temple.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of Temple University, Philadelphia, PA. The human remains and associated funerary objects were removed from the Abbott Farm National Historical Landmark, Mercer County, NJ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Temple University professional staff in consultation with representatives of the Delaware Nation, Oklahoma; Delaware Tribe of Indians; and the Stockbridge-Munsee Community, Wisconsin (hereafter referred to as ''The Tribes'').

History and Description of the Remains

Between 1963 and 1964, human remains representing, at minimum, eight individuals were removed from present-day Abbott Farm National Historical District (AFNHD) in Mercer County, NJ, by avocational archeologist Andrew Stanzeski. Stanzeski's excavations were part of a larger project led by Janet Pollack near the Watson House, which was located on Rowan Farm, now part of the AFNHD. Stanzeski gave these burials and associated funerary objects to the Temple Anthropology Laboratory and Museum at an unknown date. Eight sets of human remains were recovered from five separate burials. The human remains belong to three adult males, two adult females, one child less than 39 months of age, and one child approximately 5 years of age, and one individual of unknown age and sex. No known individuals were identified. The nine associated funerary objects are: Two lots of faunal remains, one lot of worked stone flakes, two lots of incised coarse earthenware, three worked stones (two black, one red), and one individual incised earthenware sherd.

The AFNHD is located on the Delaware River flood basin and terrace along Watson's Creek, about 3 miles south of Trenton, in Hamilton Township, Mercer County, NJ. The site was periodically occupied from the Archaic period to the present, but the assemblage of human skeletal remains at Temple University dates to the Late Woodland period (A.D. 900–1600). According to the original excavation notes, the remains of the eight individuals started to appear around 38–46 centimeters below the surface, beneath the second humus layer.

Based on geographic, ethnographic, and historic information, the AFNHD lies within the territory of the Delaware Tribes. The archeological evidence provided by the site is consistent with the use of the area by the Delaware Tribes and demonstrates cultural continuity throughout the Woodland period. In addition, linguistic, folkloric, and oral traditional information show a relationship of shared group identity between the Delaware Tribes and the earlier Woodland Period group, as well as established kinship ties between the members of the Delaware Tribes and the 17th/18th century Delaware residents of the Abbott Farm vicinity.

Determinations Made by Temple University

Officials of Temple University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of eight individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the nine objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Leslie Reeder-Myers, Temple University, 1115 Polett Walk, Gladfelter Hall Room 204, Philadelphia, PA 19122, telephone (215) 204–1418, email *leslie.reeder-myers@temple.edu,* by May 17, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

Temple University is responsible for notifying The Tribes that this notice has been published.

Dated: April 6, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–07700 Filed 4–14–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0031674; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Mississippi Department of Archives and History, Jackson, MS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Mississippi Department of Archives and History has completed an inventory of human remains, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request to the Mississippi Department of Archives and History. If no additional requestors come forward, transfer of control of the human remains to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these

human remains should submit a written request with information in support of the request to the Mississippi Department of Archives and History at the address in this notice by May 17, 2021.

ADDRESSES: Meg Cook, Director of Archaeology Collections, Mississippi Department of Archives and History, Museum Division, 222 North Street, P.O. Box 571, Jackson, MS 39205, telephone (601) 576–6927, email *mcook@mdah.ms.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains under the control of the Mississippi Department of Archives and History, Jackson, MS. The human remains were removed from the Delta region of Mississippi along the Mississippi River, and from Northeast Mississippi in the Tombigbee Hills region, including DeSoto, Lee, and Tunica counties.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of human remains was made by the Mississippi Department of Archives and History professional staff in consultation with representatives from the Alabama-Coushatta Tribe of Texas [previously listed as Alabama-Coushatta Tribes of Texas]; Alabama-Quassarte Tribal Town; Coushatta Tribe of Louisiana; Eastern Band of Cherokee Indians; Miami Tribe of Oklahoma; Mississippi Band of Choctaw Indians; Quapaw Nation [previously listed as The Quapaw Tribe of Indians]; The Chickasaw Nation; The Choctaw Nation of Oklahoma; The Muscogee (Creek) Nation; and The Osage Nation [previously listed as Osage Tribe] (hereafter referred to as ''The Tribes'').

History and Description of the Remains

At an unknown date, human remains representing, at minimum, four individuals were removed from the following sites in DeSoto County, MS, and subsequently transferred from the CH Nash Museum at Chucalissa: ''22DE526 or 527'' and ''From box 22DS501, 22DS513, 22DS512.'' No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, nine individuals were removed from the following sites in Lee County, MS: 22Le3, Thompson Place (22Le6), Martin Place (22Le7), 22Le10, 22Le11, 22Le13, 22Le18, 22Le21, and Meadowbrook (22LE912). No known individuals were identified. No associated funerary objects are present.

At an unknown date, human remains representing, at minimum, three individuals were removed from the following sites in Tunica County, MS, and subsequently transferred from the CH Nash Museum at Chucalissa: Commerce (22TU504) and West/Hood Mounds (22TU520). No known individuals were identified. No associated funerary objects are present.

The Mississippi Department of Archives and History has determined that the remains of each of these individuals are Native American through the circumstances of acquisition, as well as through the observance of biological markers consistent with this ancestry. The circumstances of acquisition, including other material culture from these collections, show that these human remains are affiliated with indigenous people in these areas of Mississippi. Individuals from DeSoto and Tunica counties are representative of the Woodland and Mississippian periods. Individuals from Lee County are representative of Proto-Historic period sites. Present day Indian Tribes affiliated with these cultures include The Tribes.

Determinations Made by the Mississippi Department of Archives and History

Officials of the Mississippi Department of Archives and History have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 16 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains should submit a written request with information in support of the request to Meg Cook, Director of Archaeology Collections, Mississippi Department of Archives and History, Museum Division, 222 North Street, P.O. Box 571, Jackson, MS 39205, telephone (601) 576–6927, email *mcook@mdah.ms.gov,* by May 17, 2021. After that date, if no additional requestors have come forward, transfer of control of the human remains to The Tribes may proceed.

The Mississippi Department of Archives and History is responsible for notifying The Tribes that this notice has been published.

Dated: April 6, 2021.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2021–07698 Filed 4–14–21; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Interchangeable Virtual Instruments Foundation, Inc.

Notice is hereby given that, on April 2, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Interchangeable Virtual Instruments Foundation, Inc. (''IVI Foundation'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, TSEP—Technical Software Engineering Plazotta, Wolnzach, GERMANY, has been added as a party to this venture.

Also, Konrad Technologies GmbH, Rodolfzell, GERMANY, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and IVI Foundation intends to file additional written notifications disclosing all changes in membership.

On May 29, 2001, IVI Foundation filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on July 30, 2001 (66 FR 39336).

The last notification was filed with the Department on December 30, 2019.

A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on January 27, 2020 (85 FR 4705).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–07717 Filed 4–14–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Subcutaneous Drug Development & Delivery Consortium, Inc.

Notice is hereby given that, on March 31, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Subcutaneous Drug Development & Delivery Consortium, Inc. (''Subcutaneous Drug Development & Delivery Consortium, Inc.'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Novartis Pharma AG, Basel, SWITZERLAND, has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Subcutaneous Drug Development & Delivery Consortium, Inc. intends to file additional written notifications disclosing all changes in membership.

On October 26, 2020, Subcutaneous Drug Development & Delivery Consortium, Inc. filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on December 3, 2020 (85 FR 78148).

The last notification was filed with the Department on January 8, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on January 28, 2021 (86 FR 7415).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–07718 Filed 4–14–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—PXI Systems Alliance, Inc.

Notice is hereby given that, on April 2, 2021, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), PXI Systems Alliance, Inc. (''PXI Systems'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, beltronic Industrie-PC AG, Rüdlingen, SWITZERLAND has been added as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and PXI Systems intends to file additional written notifications disclosing all changes in membership.

On November 22, 2000, PXI Systems filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 8, 2001 (66 FR 13971).

The last notification was filed with the Department on January 18, 2021. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on February 12, 2021 (86 FR 9371).

Suzanne Morris,

Chief, Premerger and Division Statistics, Antitrust Division.

[FR Doc. 2021–07716 Filed 4–14–21; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Excavations (Design of Cave-In Protection Systems)

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety and Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 17, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie by telephone at 202–693–0456, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Design of cave-in protection systems are needed by employers in the construction industry and OSHA compliance officers to ensure that cave-in protection systems are designed, installed, and used in a manner to protect workers adequately. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 21, 2020 (85 FR 67013).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not

display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Excavations (Design of Cave-in Protection Systems).

OMB Control Number: 1218–0137.

Affected Public: Private Sector, Businesses or other for-profits.

Total Estimated Number of Respondents: 22,881.

Total Estimated Number of Responses: 44,041.

Total Estimated Annual Time Burden: 44,041 hours.

Total Estimated Annual Other Costs Burden: $269,138.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–07693 Filed 4–14–21; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Division of Energy Employees Occupational Illness (DEEOIC) Authorization Forms

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of the Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 17, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Mara Blumenthal by telephone at 202–693–8538, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Office of Workers' Compensation Programs (OWCP) is the primary agency responsible for administration of the Energy Employees Occupational Illness Compensation Program Act of 2000, as amended (EEOICPA), 42 U.S.C. 7384 *et seq.* EEOICPA provides for the payment of compensation to covered employees and, where applicable, survivors of deceased employees, who sustained either an ''occupational illness'' or a ''covered illness'' in the performance of duty for the Department of Energy and certain of its contractors and subcontractors. One element of the compensation provided to covered employees is medical benefits for the treatment of their occupational or covered illnesses that are accepted as compensable. OWCP contracts with a private sector bill processing agent that handles many of the tasks associated with paying bills for medical treatment provided to covered employees under EEOICPA. This bill processing agent uses an automated system that matches incoming bills with the authorized medical treatment of covered employees before it issues payments, and a provider of medical treatment, supplies or services to covered employees must provide the bill processing agent with information necessary for creation of an authorization within the agent's automated system before a bill can be paid. The collection of this information is authorized by 20 CFR 30.400(a) and (c), 30.403, 30.404(b) and 30.700. The information collections in this ICR collect demographic, factual and medical information that OWCP and/or its bill processing agent needs to process bills for medical treatment, supplies or services. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 2, 2020 (85 FR 62327).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Division of Energy Employees Occupational Illness (DEEOIC) Authorization Forms.

OMB Control Number: 1240–0NEW.

Affected Public: Businesses or other for-profits institutions; Individuals or Households.

Total Estimated Number of Respondents: 12,890.

Total Estimated Number of Responses: 66,770.

Total Estimated Annual Time Burden: 11,129 hours.

Total Estimated Annual Other Costs Burden: $0.

Authority: 44 U.S.C. 3507(a)(1)(D).

Dated: April 7, 2021.

Mara Blumenthal,

Senior PRA Analyst.

[FR Doc. 2021–07692 Filed 4–14–21; 8:45 am]

BILLING CODE 4510–CR–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Powered Industrial Trucks Standard

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Occupational Safety and Health Administration (OSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for

review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before May 17, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) if the information will be processed and used in a timely manner; (3) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (4) ways to enhance the quality, utility and clarity of the information collection; and (5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Crystal Rennie by telephone at 202–693–0456, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: The Standard contains several information collection requirements addressing truck design, construction, and modification, as well as certification of training and evaluation for truck operators. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on October 16, 2020 (85 FR 65876).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OSHA.

Title of Collection: Powered Industrial Trucks Standard.

OMB Control Number: 1218–0242.

Affected Public: Private Sector, Businesses or other for-profits.

Total Estimated Number of Respondents: 1,276,055.

Total Estimated Number of Responses: 2,526,588.

Total Estimated Annual Time Burden: 450,022 hours.

Total Estimated Annual Other Costs Burden: $256,626.

Authority: 44 U.S.C. 3507(a)(1)(D).

Crystal Rennie,

Senior PRA Analyst.

[FR Doc. 2021–07694 Filed 4–14–21; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2011–0047]

Bloodborne Pathogens Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements contained in the Bloodborne Pathogens Standard.

DATES: Comments must be submitted (postmarked, sent, or received) by June 14, 2021.

ADDRESSES:

Electronically: You may submit comments, including attachments, electronically at *http://www.regulations.gov,* the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and the OSHA docket number for this **Federal Register** notice (OSHA–2011–0047). OSHA will place comments and requests to speak, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates. For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of a continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance process to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, the reporting burden (time and costs) is minimal, the collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act, or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires OSHA to obtain such information with a minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining said information (29 U.S.C. 657).

The information collection requirements specified in the Bloodborne Pathogens Standard require

employers to: Develop and maintain exposure control plans; develop a housekeeping schedule; provide workers with Hepatitis B Virus (HBV) vaccinations, post-exposure medical evaluations and follow-up; maintain medical and training records for specified periods; and provide employees and their authorized representatives with access to these records. Employers must also establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply—for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The agency is requesting an adjustment increase of 32,816.66 burden hours (from 5,687,682.00 hours to 5,720,498.66). This increase is a result of updated data showing an increase in the number of facilities (from 700,724 to 701,563) and employees (from 8,399,358 to 8,425,607) affected by the Standard.

The operation and maintenance cost increased $708,649.41, from $51,817,985.00 to $52,526,634.41, due to the increase in medical costs (administration of the Hepatitis B Vaccine and the PEP treatment). This increase is also a result of updated data showing an increase in the number of facilities and employees affected by the Standard.

The agency will summarize the comments submitted in response to this notice and will include this summary in the request to OMB.

Type of Review: Extension of a currently approved collection.

Title: Bloodborne Pathogens Standard.

OMB Control Number: 1218–0180.

Affected Public: Business or other for-profits.

Number of Respondents: 701,563.

Frequency of Responses: On occasion.

Total Responses: 26,841,471.

Average Time per Response: Varies.

Estimated Total Burden Hours: 5,720,498.66.

Estimated Cost (Operation and Maintenance): $52,526,634.41.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax); or (3) by hard copy. *Please note:* While OSHA's Docket Office is continuing to accept and process submissions by regular mail, due to the COVID–19 pandemic, the Docket Office is closed to the public and not able to receive submissions to the docket by hand, express mail, messenger, and courier service. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2011–0047). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify electronic comments by your name, date, and the docket number so that the agency can attach them to your comments.

Due to security procedures, the use of regular mail may cause a significant delay in the receipt of comments.

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download through this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office at (202) 693–2350, (TTY (877) 889–5627) for information about materials not available through the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1–2012 (77 FR 3912).

Signed at Washington, DC, on April 6, 2021.

James S. Frederick,

Principal Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2021–07695 Filed 4–14–21; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Notice of Controversion of Right to Compensation

AGENCY: Division of Federal Employees Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Notice of Controversion of Right to Compensation.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by June 14, 2021.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained for free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

Submit written comments about this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; or by email at *suggs.anjanette@dol.gov.* Please note that comments submitted after the comment period will not be considered.

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)] This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation (OWCP) is soliciting comments concerning the proposed collection: Notice of Controversion of Right to Compensation (LS–207). A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

Legal authority for this information collection is found at 33 U.S.C. 914(d).

Regulatory authority is found at 20 CFR 702.251.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Written comments will receive consideration, and summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB No. 1240–0042.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL-Office of Workers' Compensation Programs, DFELHWC.

Type of Review: Extension of currently approved collection.

Title of Collection: Longshore and Harbor Workers' Compensation Act Notice of Controversion of Right to Compensation.

Form: LS–207, Notice of Controversion of Right to Compensation.

OMB Control Number: 1240–0042.

Affected Public: Private Sector.

Estimated Number of Respondents: 550.

Frequency: On occasion.

Total Estimated Annual Responses: 19,250.

Estimated Average Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 4,813 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2021–07697 Filed 4–14–21; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Agency Information Collection Activities; Comment Request; Notice of Payments

AGENCY: Division of Federal Employees', Longshore and Harbor Workers' Compensation, Office of Workers' Compensation Programs.

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is soliciting comments concerning a proposed extension for the authority to conduct the information collection request (ICR) titled, ''Notice of Payments.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by June 14, 2021.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained for free by contacting Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

Submit written comments about this ICR by mail or courier to the U.S. Department of Labor, Office of Workers' Compensation Programs, Room S3323, 200 Constitution Avenue NW, Washington, DC 20210; or by email at *suggs.anjanette@dol.gov.* Please note that comments submitted after the comment period will not be considered.

FOR FURTHER INFORMATION CONTACT: Anjanette Suggs by telephone at 202–354–9660 or by email at *suggs.anjanette@dol.gov.*

SUPPLEMENTARY INFORMATION: The DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the OMB for final approval. This program helps to

ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed.

The Office of Workers' Compensation Programs administers the Longshore and Harbor Workers' Compensation Act. The Act provides benefits to workers injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

Under sections 914(b) & (c) of the Longshore Act, a self-insured employer or insurance carrier is required to pay compensation within 14 days after the employer has knowledge of the injury or death and immediately notify the district director of the payment. Under Section 914(g), the employer/carrier is required to issue notification of final payment of compensation. Form LS–208 has been designated as the proper form on which report of those payments is to be made.

Legal authority for this information collection is found at 33 U.S.C. 914(b), (c) & (g).

Regulatory authority is found at 20 CFR 702.234.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB under the PRA approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Written comments will receive consideration, and summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB No. 1240–0041.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. The DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

The DOL is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL-Office of Workers' Compensation Programs, DFELHWC.

Type of Review: Extension of currently approved collection.

Title of Collection: Longshore and Harbor Workers' Compensation Act Notice of Payments.

Form: LS–208, Notice of Payments.

OMB Control Number: 1240–0041.

Affected Public: Private Sector.

Estimated Number of Respondents: 550.

Frequency: On occasion.

Total Estimated Annual Responses: 33,000.

Estimated Average Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 5,500 hours.

Total Estimated Annual Other Cost Burden: $0.

Authority: 44 U.S.C. 3506(c)(2)(A).

Anjanette Suggs,

Agency Clearance Officer.

[FR Doc. 2021–07696 Filed 4–14–21; 8:45 am]

BILLING CODE 4510–CF–P

LEGAL SERVICES CORPORATION

Notice to LSC Grantees of Application Process for Subgranting 2021 Basic Field Grant Funds Midyear

AGENCY: Legal Services Corporation (LSC).

ACTION: Notice of application dates and format for applications to make midyear subgrants of 2021 Basic Field Grant funds.

SUMMARY: The Legal Services Corporation (LSC) is the national organization charged with administering Federal funds provided for civil legal services to low-income people. LSC is announcing the submission dates for applications to make subgrants of Basic Field Grant funds starting after April 15, 2021 but before January 1, 2022. LSC is also providing information about where applicants may locate subgrant application forms and directions for providing the information required in the application.

DATES: See the **SUPPLEMENTARY INFORMATION** section for application dates.

ADDRESSES: Legal Services Corporation—Office of Compliance and Enforcement, 3333 K Street NW, Third Floor, Washington, DC 20007–3522.

FOR FURTHER INFORMATION CONTACT: Megan Lacchini, Office of Compliance and Enforcement by email at *lacchinim@lsc.gov* or (202) 295–1506, or visit the LSC website at *http://www.lsc.gov/grants-grantee-resources/grantee-guidance/how-apply-subgrant.*

SUPPLEMENTARY INFORMATION: Under 45 CFR part 1627, LSC must publish, on an annual basis, ''notice of the requirements concerning the format and contents of the application annually in the **Federal Register** and on its website.'' 45 CFR 1627.4(b). This Notice and the publication of the Subgrant Application Forms on LSC's website satisfy section1627.4(b)'s notice requirement for midyear subgrants of Basic Field Grant funds. Only current or prospective recipients of LSC Basic Field Grants may apply for approval to subgrant these funds.

An applicant must submit an application to make a midyear subgrant of LSC Basic Field Grant funds at least 45 days in advance of the subgrant's proposed effective date. 45 CFR 1627.4(b)(2). Applications must be submitted through GrantEase.

All applicants must provide answers to the application questions in GrantEase and upload the following documents:

- A draft subgrant agreement (with the required terms provided in LSC's Subgrant Agreement Template); and
- A subgrant budget (using LSC's Subgrant Budget Template)

Applicants seeking to subgrant to a new subrecipient that is not a current LSC grantee, or to renew a subgrant with an organization that is not a current LSC grantee in a year in which the applicant is required to submit a full funding application, must also upload:

- The subrecipient's accounting manual;

• The subrecipient's most recent audited financial statements;

• The subrecipient's current cost allocation policy (if not in the accounting manual);

• The subrecipient's 45 CFR 1635.3(c) recordkeeping policy (if not in the accounting manual)

LSC's Subgrant Agreement Template and the Subgrant Budget Template are available on LSC's website at *http://www.lsc.gov/grants-grantee-resources/grantee-guidance/how-apply-subgrant.*

LSC encourages applicants to use LSC's Subgrant Agreement Template as a model subgrant agreement. If the applicant does not use LSC's Template, the proposed agreement must include, at a minimum, the substance of the provisions of the Template.

Once submitted, LSC will evaluate the application and provide applicants with instructions on any needed modifications to the submitted documents or Draft Agreement provided with the application. The applicant must then upload a final and signed subgrant agreement through GrantEase by the date requested.

As required by 45 CFR 1627.4(b)(3), LSC will inform applicants of its decision to disapprove, approve, or request modifications to the subgrant by no later than the subgrant's proposed effective date.

Dated: April 12, 2021.

Stefanie Davis,

Senior Assistant General Counsel.

[FR Doc. 2021–07741 Filed 4–14–21; 8:45 am]

BILLING CODE 7050–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–019]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of a request for comments regarding an information collection.

SUMMARY: We are planning to request that the Office of Management and Budget (OMB) renew its approval for us to engage in the following generic information collection request (generic ICR), and we invite you to comment on it: Generic Clearance for NARA Public and Education Program Registration. Under this information collection, we request registration and attendance information from people requesting to attend an education or other program at NARA.

DATES: We must receive written comments on or before June 14, 2021.

ADDRESSES: Send comments by email to *tamee.fechhelm@nara.gov*. Because our buildings are temporarily closed during the COVID–19 restrictions, we are not able to receive comments by mail during this time.

FOR FURTHER INFORMATION CONTACT: Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gov* or by telephone at 301–837–1694 with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite comments proposed information collections. Comments and suggestions should address one or more of the following points: (a) Whether the proposed information is necessary for NARA to properly perform its functions; (b) our estimates of the burden of the proposed information collections and their accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether these collections affect small businesses. Burden means the total time, effort, or financial resources people need to provide the information, including time to review instructions, process and maintain the information, search data sources, and respond.

We will summarize any comments you submit and include the summary in our request for OMB approval. All comments will become a matter of public record. For this reason, please do not include in your comments information of a confidential nature, such as sensitive personal information or proprietary information.

Explanation of generic ICRs

A generic ICR is a request for OMB to approve a plan for conducting more than one information collection using very similar methods when (1) we can evaluate the need for and the overall practical utility of the data in advance, as part of the review of the proposed plan, but (2) we cannot determine the details of the specific individual collections until a later time. Most generic clearances cover collections that are voluntary, low-burden (based on a consideration of total burden, total respondents, or burden per respondent), and uncontroversial. This notice, for example, describes a general plan to gather registration information from members of the public who wish to participate in programs at NARA, through a series of registration forms used for a variety of current and future education programs at different facilities. As part of this plan, we construct, distribute, and use the registration forms in a similar manner, but customize each one for the type and location of the program involved.

Because we seek public comment on the plan, we do not need to seek public comment on each specific information collection that falls within the plan when we later develop the individual information collection. This saves the Government time and burden, and it streamlines our ability to gather registration information so we can provide more responsive programs. However, we still submit each specific information collection (*e.g.,* each form) to OMB for review, in accordance with the terms of clearance set upon approval of the plan. OMB assesses the individual forms for PRA requirements, ensures that they fit within the scope of this generic ICR plan, and includes the specific forms in the PRA public docket prior to our use of them.

Specifics on This Information Collection

Title: Generic Clearance for NARA Public and Education Program Registration.

Description: This generic information collection request allows us to gather information from those members of the public who wish to register for public events, education programs, tours, and training sponsored by NARA. We will not use these forms for quantitative information collections designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance.

Purpose: Collecting this information allows us to register participants for NARA's public, education, and training programs throughout the agency's locations, and to collect and process credit card payments. The information is also used to develop mailing lists for distribution of education-related information and special NARA training events, based on the request or expressed interest of the person registering. Advance registration allows NARA offices to schedule the tours, training, and events to maximize the participants' time and to accommodate the participants in the space. The information collected from registrants will help ensure that users have an effective, efficient, and satisfying

experience with our programs, in compliance with E.O. 12862. Without the ability to collect this information, NARA would not be able to effectively organize events, resulting in possibly turning away members of the public from events that might be overbooked.

Conditions: We will submit a specific information collection for approval under this generic clearance only if it meets the following conditions:

- The collection is voluntary;
- The collection is low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and is low-cost for both the respondents and the Federal Government;
- The collection is non-controversial and does not raise issues of concern to other Federal agencies;
- Personally identifiable information (PII) is collected only to the extent necessary and is retained only for the period of time required by NARA records schedules;
- Information gathered will be used only internally for program management purposes and is not intended for release outside of the agency;
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collections will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

As a general matter, information collections under this generic collection request will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private. In this notice, NARA solicits comments concerning the following information collection:

Title: Generic Clearance for NARA Public and Education Program Registration.

OMB number: 3095–0074.

Agency form numbers: NA 2027, 2029, 2030, 2032, 11009, 11009C.

Type of review: Regular.

Projected affected public: Individuals or households, business or other for-profit, not-for-profit institutions, schools, Federal, state, local, or tribal government organizations.

Projected average estimates for the next three years:

Average expected annual number of forms: 6.

Average projected number of respondents per form: 1.

Estimated number of respondents in total: 7,921.

Estimated time per response: 5–10 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 1,300 hours.

Abstract: We offer a variety of education programs, public programs, tours, training, and events throughout the country. In order to register participants, we use various online and paper registration forms. Advance registration allows NARA offices to schedule the tours, training, and events to maximize the participants' time and to accommodate the participants in the space.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2021–07715 Filed 4–14–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Office of Government Information Services

[NARA–2021–023]

Meetings; Chief Freedom of Information Act (FOIA) Officers Council

AGENCY: Office of Government Information Services (OGIS), National Archives and Records Administration (NARA), and Office of Information Policy (OIP), U.S. Department of Justice (DOJ).

ACTION: Notice of meeting.

SUMMARY: We are announcing a meeting of the Chief Freedom of Information Act (FOIA) Officers Council, co-chaired by the Director of OGIS and the Director of OIP.

DATES: The meeting will be on Thursday April 29, 2021, from 9:30 a.m. to 11:30 a.m. EDT. Please register for the meeting no later than 11:59 p.m. EDT on Tuesday, April 27, 2021 (registration information is detailed below).

Location: The April 29, 2021, meeting will be a virtual meeting. We will send access instructions to those who register according to the instructions below.

FOR FURTHER INFORMATION CONTACT: Martha Murphy by email at *ogis@nara.gov* with the subject line ''Chief FOIA Officers Council'' or by telephone at 202.741.5770.

SUPPLEMENTARY INFORMATION: This meeting is open to the public in accordance with the Freedom of Information Act (5 U.S.C. 552(k)). Additional details about the meeting are available on OGIS's website at *https://www.archives.gov/ogis/about-ogis/chief-foia-officers-council* and OIP's website at *https://www.justice.gov/oip/chief-foia-officers-council.*

Procedures: This virtual meeting is open to the public. You must register through Eventbrite in advance if you wish to attend and/or submit oral statements. You must also include an email address so that we can provide you access information. We will live-stream the meeting on the National Archives' YouTube channel at *https://www.youtube.com/user/usnationalarchives,* and will include a captioning option. To request additional accommodations (*e.g.,* a transcript), email *ogis@nara.gov* or call 202–741–5770. Members of the media who wish to register, those who are unable to register online, and those who require special accommodations, should contact Martha Murphy (contact information above).

Alina M. Semo,

Director, Office of Government Information Services.

[FR Doc. 2021–07713 Filed 4–14–21; 8:45 am]

BILLING CODE 7515–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91524; File No. SR–Phlx–2021–07]

Self-Regulatory Organizations; Nasdaq PHLX LLC; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Permit the Listing and Trading of Options Based on 1/100th the Value of the Nasdaq-100 Index

April 9, 2021.

I. Introduction

On February 10, 2021, Nasdaq PHLX LLC (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to permit the listing and trading of index options on based on 1/100th the value of the Nasdaq-100 Index. The proposed rule change was published for comment in the **Federal Register** on February 26, 2021.[3] On March 17, 2021, the Exchange filed Amendment No. 1 to the proposed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 91178 (February 22, 2021), 86 FR 11807.

rule change.[4] The Commission is approving the proposed rule change, as modified by Amendment No. 1, subject to a pilot period set to expire on November 4, 2021.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange is proposing to amend its rules to permit the listing and trading of index options on the Nasdaq 100 Micro Index (''XND'') on a pilot basis. The Exchange states that the XND options contract will be the same in all respects as the current Nasdaq-100 Index (''NDX'') options contract listed on the Exchange,[5] except that it will be based on 1/100th of the value of the Nasdaq-100 Index, and will be P.M.-settled with an exercise settlement value based on the closing index value of the Nasdaq-100 Index on the day of expiration.[6] In particular, XND options will be subject to the same rules that presently govern the trading of index options based on the Nasdaq-100 Index, including sales practice rules, margin requirements, trading rules, and position and exercise limits. Like NDX options, XND options will be European-style and cash-settled, and will have a contract multiplier of 100. XND options will have a minimum trading increment of $0.01 for all series.[7] Strike price intervals will be set at $2.50 or greater, subject to conditions described in Options 4A, Section 12(a)(2).[8] Consistent with the Exchange's existing rules for index options, the Exchange will allow up to six expiration months at any one time that may expire at three-month intervals or in consecutive months, as well as LEAPS.[9] The Exchange states that, pursuant to Phlx Options 4A, Section 12(b)(5), XND options may be listed and traded in accordance with the Nonstandard Expirations Pilot Program, which permits the Exchange to list Weekly Expirations [10] and End of Month (''EOM'') Expirations [11] on any broad-based index [12] eligible for standard options trading. XND options will have European-style exercise and will not be subject to position limits, although the Exchange proposes to amend Options 4A, Section 6 to describe how positions in micro index value options would be aggregated with full value and reduced value options.[13]

As proposed, XND options would be subject to a pilot for a period that would end on November 4, 2021 (''Pilot Program''). If the Exchange were to propose an extension of the Pilot Program or should the Exchange propose to make the Pilot Program permanent, then the Exchange would submit a filing proposing such amendments to the Pilot Program. The Exchange notes that any positions established under the pilot would not be impacted by the expiration of the pilot. For example, a position in an XND options series that expires beyond the conclusion of the pilot period could be established during the pilot. If the Pilot Program were not extended, then the position could continue to exist. However, the Exchange notes that any further trading in the series would be restricted to transactions where at least one side of the trade is a closing transaction.

The Exchange proposes to submit a Pilot Program report to Commission at least two months prior to the expiration date of the Pilot Program (the ''annual report''). The annual report would contain an analysis of volume, open interest, and trading patterns. The analysis would examine trading in the proposed option product as well as trading in the securities that comprise the Nasdaq-100 Index. In addition, for series that exceed certain minimum open interest parameters, the annual report would provide analysis of index price volatility and share trading activity. In addition to the annual report, the Exchange would provide the Commission with periodic interim reports while the Pilot Program is in effect that would contain some, but not all, of the information contained in the annual report. The annual report would be provided to the Commission on a confidential basis. The annual report would contain the following volume and open interest data:

(1) Monthly volume aggregated for all trades;

(2) monthly volume aggregated by expiration date;

(3) monthly volume for each individual series;

(4) month-end open interest aggregated for all series;

(5) month-end open interest for all series aggregated by expiration date; and

(6) month-end open interest for each individual series.

In addition to the annual report, the Exchange would provide the Commission with interim reports of the information listed in items (1) through (6) above periodically as required by the Commission while the Pilot Program is in effect. These interim reports would also be provided on a confidential basis.

Finally, the annual report would contain the following analysis of trading patterns in third Friday of the month (''Expiration Friday''), P.M.-settled XND option series in the Pilot Program: (1) A time series analysis of open interest; and (2) an analysis of the distribution of trade sizes. Also, for series that exceed certain minimum parameters, the

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[4] In Amendment No. 1, the Exchange amended the proposal to: (1) Extend the duration of the proposed pilot period for XND options from May 4, 2021 to November 4, 2021; and (2) specify that the Exchange intends to begin implementation of the proposed rule change prior to May 1, 2021. Because Amendment No. 1 to the proposed rule change is technical in nature and does not materially alter the substance of the proposed rule change or raise any novel regulatory issues, it is not subject to notice and comment. Amendment No. 1, which amended and replaced the original proposal in its entirety, is available on the Commission's website at: *https://www.sec.gov/comments/sr-phlx-2021-07/srphlx202107-8513064-230103.pdf.*

[5] *See* Options 4A, Section 12(e)(II).

[6] The Exchange notes that similar features are available with other index options contracts listed or approved for trading on the Exchange and other options exchanges, including the Exchange's affiliate, Nasdaq ISE, LLC (''ISE''), which lists options contracts based on 1/5th the value of the Nasdaq-100 (''NQX''). *See* Amendment No. 1, *supra* note 4, at 5.

[7] More specifically, the Exchange proposes that as long as QQQ options participate in the Penny Interval Program, XND options shall have a minimum increment of $.01. *See* proposed Supplementary Material .03 to Options 3, Section 3.

[8] Generally, pursuant to Options 4A, Section 12(a)(2), except as provided in Supplementary Material .04 to Options 4A, Section 12, index options listed on the Exchange are subject to strike price intervals of no less than $5, provided that certain classes of index options (including Reduced Value NDX options) have strike price intervals of no less than $2.50. The Exchange proposes to amend Options 4A, Section 12(a)(2) to add XND options to the list of classes where strike price intervals of no less than $2.50 are generally permitted, if the strike price is less than $200. The Exchange will not list long term index options series (''LEAPS'') on XND options at intervals less than $5. If the Exchange determines to add XND options to the Short Term Option Series (''STOS'') or Quarterly Option Series programs, such options will be listed with the expirations and strike prices described in Supplementary Material .02 to Options 4A, Section 12. The Exchange notes that it expects to add XND options to the STOS program. *See* Amendment No. 1, *supra* note 4 at 11, n.18.

[9] *See id.* at 11 & n.16.

[10] Weekly Expirations may expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration). *See* Options 4A, Section 12(b)(5).

[11] EOMs expire on last trading day of the month. *See* Options 4A, Section 12(b)(5).

[12] The Exchange states XND is a broad-based index. *See* Amendment No. 1, *supra* note 4, at 4, n.6. To the extent the Exchange lists XND options pursuant to the Nonstandard Expirations Pilot Program, the Exchange would be required to provide the same information with respect to XND that it does for others options listed pursuant to the Nonstandard Expirations Pilot Program in the reports and data it provides to the Commission.

[13] For a more detailed description of the proposed XND contract, *see* Amendment No. 1, *supra* note 4. The Exchange also proposes to add new Options 4A, Section 12(a)(5) titled ''European-Style Exercise'' to clarify in the Exchange's rules which Exchange-listed index options will trade European-Style Exercise, and to add rule text within Options 4A, Section 12(b)(2), which describes LEAPS, to specifically allow for the listing of long term options series on XND.

annual report would contain the following analysis related to index price changes and underlying share trading volume at the close on Expiration Fridays: A comparison of index price changes at the close of trading on a given Expiration Friday with comparable price changes from a control sample. The data would include a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by an appropriate index as agreed by the Commission and the Exchange, would be provided. The Exchange would provide a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money series. The data would include a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period. The minimum open interest parameters, control sample, time intervals, method for randomly selecting the component securities, and sample periods would be determined by the Exchange and the Commission.[14]

III. Discussion and Commission Findings

After careful consideration of the proposal, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange,[15] and, in particular, the requirements of Section 6 of the Act.[16] Specifically, the Commission finds that the proposed rule change, as Modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[17] which requires that an exchange have rules designed to remove impediments to and perfect the mechanism of a free and open market and to protect investors and the public interest, to allow the Exchange to conduct a limited, and carefully monitored, pilot as proposed.

The Commission has previously approved the listing and trading of options based on a reduced value of the Nasdaq-100 Index,[18] including P.M.-settled reduced value options,[19] and, as stated in the Commission's order approving the listing and trading of NDXPM on the Exchange on a pilot program basis, the Commission has had concerns about the potential adverse effects and impact of P.M. settlement upon market volatility and the operation of fair and orderly markets on the underlying cash market at or near the close of trading, including for cash-settled derivatives contracts based on a broad-based index.[20] The potential impact today remains unclear, given the significant changes in the closing procedures of the primary markets in recent decades. The Commission is mindful of the historical experience with the impact of P.M. settlement of cash-settled index derivatives on the underlying cash markets, but recognizes that these risks may be mitigated today by the enhanced closing procedures that are now in use at the primary equity markets.

For the reasons described below, the Commission believes that the Exchange's proposed XND Pilot Program is designed to mitigate concerns regarding P.M. settlement and will provide additional trading opportunities for investors while providing the Commission with data to monitor the effects of XND options and the impact of P.M. settlement on the markets. To assist the Commission in assessing any potential impact of a P.M.-settled XND option on the options markets as well as the underlying cash equities markets, the Exchange will be required to submit data to the Commission in connection with the Pilot Program. The Commission believes that the Exchange's proposed Pilot Program, together with the data and analysis that the Exchange will provide to the Commission, will allow the Exchange and the Commission to monitor for and assess any potential for adverse market effects of allowing P.M. settlement for XND options, including on the underlying component stocks. In particular, the data collected from the Exchange's XND Pilot Program will help inform the Commission's consideration of whether the Pilot Program should be modified, discontinued, extended, or permanently approved. Furthermore, the Exchange's ongoing analysis of the Pilot Program should help it monitor any potential risks from large P.M.-settled positions and take appropriate action on a timely basis if warranted.

The Exchange represents that it has adequate surveillance procedures to monitor trading in these options thereby helping to ensure the maintenance of a fair and orderly market, and has represented that it has sufficient capacity to handle additional traffic associated with this new listing.[21]

For the reasons discussed above, the Commission finds that the Exchange's proposal is consistent with the Act, including Section 6(b)(5) thereof, in that it is designed to remove impediments to and perfect the mechanism of a free and open market, and, in general, to protect investors and the public interest. In light of the enhanced closing procedures at the underlying markets and the potential benefits to investors discussed by the Exchange in its filing,[22] the Commission finds that it is appropriate and consistent with the Act to approve the Exchange's proposal on a pilot basis. The collection of data during the Pilot Program and the Exchange's active monitoring of any effects of XND options on the markets will help the Exchange and the Commission assess any impact of P.M. settlement in today's market.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[23] that the proposed rule change (SR–Phlx–2021–07), as modified by Amendment No. 1, be, and hereby is, approved, subject to a pilot period set to expire on November 4, 2021.

[14] *See id.* The proposed Pilot Program for XND options is similar to the pilot program approved for the listing and trading of P.M.-settled options on the full value of the Nasdaq-100 (''NDXPM'') on the Exchange and NQX options on ISE. *See* Securities Exchange Act Release Nos. 81293 (August 2, 2017), 82 FR 37138 (August 8, 2017)(''NDXPM Order'') and 82911 (March 20, 2018), 83 FR 12966 (March 26, 2018) (''NQX Order'').

[15] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f.

[17] 15 U.S.C. 78f(b)(5).

[18] *See, e.g.,* Securities Exchange Act Release Nos. 57654 (April 11, 2008), 73 FR 21003 (April 17, 2008) and 51121 (February 1, 2005), 70 FR 6476 (February 7, 2005).

[19] *See* NQX Order, *supra* note 14.

[20] *See* NDXPM Order, *supra* note 14, at 37140. *See also* Securities Exchange Act Release Nos. 64599 (June 3, 2011), 76 FR 33798, 33801–02 (June 9, 2011) (order instituting proceedings to determine whether to approve or disapprove a proposed rule change to allow the listing and trading of SPXPM options); 65256 (September 2, 2011), 76 FR 55969, 55970–76 (September 9, 2011) (order approving proposed rule change to establish a pilot program to list and trade SPXPM options); and 68888 (February 8, 2013), 78 FR 10668, 10669 (February 14, 2013) (order approving the listing and trading of SPXPM on CBOE).

[21] *See* Amendment No. 1, *supra* note 4, at 17. In addition, the Commission notes that the Exchange would have access to information through its membership in the Intermarket Surveillance Group with respect to the trading of the securities underlying the XND, as well as tools such as large options positions reports to assist its surveillance of XND options.

[22] *See* Amendment No. 1, *supra* note 4.

[23] 15 U.S.C. 78s(b)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–07677 Filed 4–14–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91523; File No. SR–IEX–2021–06]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing of Proposed Rule Change To Enhance the IEX Retail Price Improvement Program for the Benefit of Retail Investors

April 9, 2021.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on April 1, 2021, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[4] and Rule 19b–4 thereunder,[5] IEX is filing with the Commission a proposed rule change to enhance its Retail Price Improvement Program for the benefit of retail investors.

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to enhance the Exchange's Retail Price Improvement Program for the benefit of retail investors. Specifically, the Exchange proposes to make the following four changes: (i) Revise the definition of Retail order[6] in IEX Rule 11.190(b)(15) to apply only to the trading interest of a natural person that does not place more than 390 equity orders per day on average during a calendar month for its own beneficial account(s);[7] (ii) provide Order Book[8] priority to Retail Liquidity Provider (''RLP'') orders[9] at the Midpoint Price[10] ahead of other non-displayed orders priced to execute at the Midpoint Price; (iii) disseminate a ''Retail Liquidity Identifier'' through the Exchange's proprietary market data feeds and the appropriate securities information processor (''SIP'') when RLP order interest aggregated to form at least one round lot for a particular security is available in the System,[11] provided that the RLP order interest is resting at the Midpoint Price and is priced at least $0.001 better than the NBB[12] or NBO;[13] and (iv) amend the definition of RLP orders so such orders can only be midpoint peg orders,[14] cannot be Discretionary Peg orders,[15] and cannot include a minimum quantity restriction.[16] The proposed changes are designed to further support and enhance the ability of non-professional retail investors to obtain meaningful price improvement by incentivizing market participants to compete to provide such price improvement.

Background

In 2019 the Commission approved IEX's Retail Price Improvement Program (''Retail Program''),[17] which is designed to provide retail investors with meaningful price improvement opportunities through trading at the Midpoint Price or better.[18] As currently structured, Members[19] that qualify as Retail Member Organizations (''RMOs'')[20] are eligible to submit Retail orders to the Exchange. Any Member is able to provide price improvement to Retail orders through orders priced to execute at the Midpoint Price or better, including RLP orders that are only eligible to execute against a Retail order at the Midpoint Price and execute in price-time priority after other orders resting on the Order Book priced to trade at the Midpoint Price.

As IEX noted in its Retail Program rule filing,[21] the Commission has consistently emphasized the importance of continued broad, long-term retail participation in our capital markets. In its Strategic Plan for fiscal years 2018–2022, the Commission highlighted its vision to ''promote capital markets that inspire public confidence and provide a diverse array of financial opportunities to retail and institutional investors, entrepreneurs, public companies, and other market participants'', with its first goal to focus on the long-term interests of Main Street (*i.e.,* retail) investors.[22] Against this backdrop, the Retail Program is designed to provide retail

[24] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] *See* IEX Rules 11.190(b)(15) and 11.232(a)(2).

[7] The existing restrictions applicable to a Retail order, that it must reflect trading interest of a natural person with no change made to the terms of the underlying order of the natural person with respect to price (except in the case of a market order that is changed to a marketable limit order) or side of market and that does not originate from a trading algorithm or any other computerized methodology, will continue to apply.

[8] *See* IEX Rule 1.160(p).

[9] *See* IEX Rules 11.190(b)(14) and 11.232(a)(3).

[10] The term ''Midpoint Price'' means the midpoint of the NBBO. *See* IEX Rule 1.160(t). The term ''NBBO'' means the national best bid or offer, as set forth in Rule 600(b) of Regulation NMS under the Act, determined as set forth in IEX Rule 11.410(b).

[11] *See* IEX Rule 1.160(nn).

[12] *See* IEX Rule 1.160(u).

[13] *See* IEX Rule 1.160(u).

[14] *See* IEX Rule 11.190(b)(9).

[15] *See* IEX Rule 11.190(b)(10).

[16] *See* IEX Rule 11.190(b)(11).

[17] *See* Securities Exchange Act Release No. 86619 (August 9, 2019), 84 FR 41769 (August 15, 2019) (SR–IEX–2019–05) (SEC order approving IEX's Retail Program).

[18] On March 1, 2021, IEX filed an immediately effective rule change proposal to provide that, in addition to executing at the Midpoint Price, a Retail order can execute against a displayed unprotected odd lot order that is resting on the Order Book at a price more aggressive than the Midpoint Price (*i.e.,* above the Midpoint Price in the case of an odd lot buy order and below the Midpoint Price in the case of an odd lot sell order). Executing against such an odd lot order thus provides more price improvement to the Retail order than executing at the Midpoint Price. *See* Securities Exchange Act Release No. 91324 (March 15, 2021), 86 FR 15015 (March 19, 2021) (SR–IEX–2021–03).

[19] *See* IEX Rule 1.160(s).

[20] *See* IEX Rule 11.232(a)(1).

[21] *See supra* note 17. *See also* Securities Exchange Act Release No. 86241 (June 28, 2019), 84 FR 32238 (July 5, 2019) (SR–IEX–2019–05) (IEX rule filing proposing Retail Program).

[22] *See* U.S. Securities and Exchange Commission, Strategic Plan, Fiscal Years 2018–2022, available at *https://www.sec.gov/files/SEC_Strategic_Plan_FY18-FY22_FINAL_0.pdf* (''Commission Strategic Plan'').

investors with access to the Exchange's deep pool of midpoint liquidity, including RLP orders, thereby providing enhanced opportunities for meaningful price improvement at the Midpoint Price. The Exchange believes the Retail Program has provided retail investors with better execution quality than they are currently able to obtain through existing exchange and over-the-counter (''OTC'') order retail programs, by attracting counterparty liquidity to the Exchange from Members and their clients seeking to interact with retail liquidity.[23] The Retail Program is therefore consistent with the goals of the Commission to encourage markets that are structured to benefit ordinary investors.[24]

Under the current Retail Program, the term ''Retail order'' is defined as an agency or riskless principal order that satisfies the criteria of Financial Industry Regulatory Authority, Inc. (''FINRA'') Rule 5320.03, which is submitted by a RMO, designated with a ''Retail order'' modifier, and reflects trading interest of a natural person, with no change made to the terms of the underlying order of the natural person with respect to price (except in the case of a market order that is changed to a marketable limit order) or side of market, and that does not originate from a trading algorithm or any other computerized methodology.[25] Retail orders may either be Discretionary Peg or midpoint peg orders with a Time-in-Force of IOC or FOK, and are only eligible to trade at the Midpoint Price or better.[26]

An RMO is an IEX Member (or division thereof) that has been approved by the Exchange to submit Retail orders.[27] Pursuant to IEX Rules 11.232(a)(1) and (b), which describe the qualification and application process for becoming an RMO, any Member may qualify as an RMO if it conducts a retail business or routes Retail orders on behalf of another broker-dealer.

An RLP order is currently a Discretionary Peg order that is only eligible to execute against Retail orders through the execution process described in IEX Rule 11.232(e).[28] Any Member can submit RLP orders.

As discussed in the Retail Program rule filing,[29] IEX's Retail Program is a simple approach designed to provide retail investors with the opportunity for meaningful price improvement (by executing at the Midpoint Price or better), by attracting counterparty liquidity to the Exchange from Members and their clients seeking to interact with retail liquidity.

IEX's Retail Program leverages IEX's market structure to provide enhanced price improvement opportunities for retail customers by incentivizing Members and their clients to provide liquidity to the orders of retail investors, while enabling such investors to obtain materially better price improvement than may otherwise be available, in a way that is mutually beneficial for retail investors and Members providing liquidity. Based on experience with the Retail Program, IEX believes that the four proposed changes, noted above and described in detail below, would further enhance the Retail Program.

Proposal

IEX proposes four enhancements to the Retail Program, as described below.

Retail Order Definition

IEX proposes to revise the definition of Retail order in IEX Rule 11.190(b)(15) so that it is limited to retail investors who do not appear to be engaged in trading activity akin to that of a professional. Specifically, the definition of Retail order would be amended to apply only to the trading interest of a natural person that does not place more than 390 equity orders per day on average during a calendar month for its own beneficial account(s). All other existing criteria specified in IEX Rule 11.190(b)(15) would continue to apply.

IEX Rule 11.190(b)(15) currently provides that a Retail order means an order submitted by a Retail Member Organization (as defined in IEX Rule 11.232) and designated with a ''Retail order'' modifier. A Retail order must be an agency order, or riskless principal order that satisfies the criteria of FINRA Rule 5320.03. A Retail order must reflect trading interest of a natural person with no change made to the terms of the underlying order of the natural person with respect to price (except in the case of a market order that is changed to a marketable limit order) or side of market and that does not originate from a trading algorithm or any other computerized methodology, which will now be defined as a ''retail customer'' for clarity. An order from a retail customer can include orders submitted on behalf of accounts that are held in a corporate legal form—such as an Individual Retirement Account, Corporation, or a Limited Liability Company—that have been established for the benefit of an individual or group of related family members, provided that the order is submitted by an individual. IEX proposes to add new language to IEX Rule 11.190(b)(15) to specify that a Retail order may only be submitted on behalf of a retail customer that does not place more than 390 equity orders per day on average during a calendar month for its own beneficial account(s).

In addition, IEX proposes to add Supplementary Material .01 to IEX Rule 11.190(b) specifying how to determine whether the 390 equity orders per day on average threshold has been reached. Specifically, the Supplementary Material would provide that a ''parent'' order that is broken into multiple ''child'' orders by a broker or dealer, or by an algorithm housed at a broker or dealer or by an algorithm licensed from a broker or dealer, but which is housed with the customer, counts as one order even if the ''child'' orders are routed across multiple exchanges. In addition, any order that cancels and replaces an existing order would count as a separate order; except that an order that cancels and replaces any ''child'' order resulting from a ''parent'' order that is broken into multiple ''child'' orders, does not count as a new order.

IEX also proposes to add Supplementary Material .02 to IEX Rule 11.190(b) to address the reasonable policies and procedures that an RMO must have in place to ensure that Retail orders are appropriately represented on the Exchange. Specifically, such policies and procedures should provide for a review of retail customers' activity on at least a quarterly basis. Further, Retail orders for any retail customer that had an average of more than 390 equity orders per day during any month of a calendar quarter are not eligible to be entered as Retail orders for the next calendar quarter. Retail Member Organizations must conduct a quarterly review and make any appropriate changes to the way in which they are representing orders within five business days after the end of each calendar quarter. In addition, if during a quarter the Exchange identifies a retail customer for which orders are being represented as Retail orders but that has averaged more than 390 equity orders per day during a month, the Exchange will

[23] *See* discussion *infra* on the desirability of interacting with retail liquidity.

[24] *See supra* note 22.

[25] *See supra* note 6. An order from a natural person can include orders submitted on behalf of accounts that are held in a corporate legal form—such as an Individual Retirement Account, Corporation, or a Limited Liability Company—that have been established for the benefit of an individual or group of related family members, provided that the order is submitted by an individual.

[26] *See* IEX Rule 11.232(a)(2). As with all pegged orders, Retail orders may only trade during the Regular Market Session. *See* IEX Rule 11.190(a)(3)(E).

[27] *See* IEX Rule 11.232(a)(1).

[28] *See* IEX Rule 11.232(e).

[29] *See supra* note 21.

notify the RMO, and the RMO will be required to change the manner in which it is representing the retail customer's orders within five business days.

As noted above, the Exchange believes that the price improvement benefits that accrue to Retail orders on IEX should be limited to retail customers who do not appear to be engaged in trading activity akin to that of a professional. IEX notes that the 390-order limitation is a threshold used by various options exchanges to distinguish professional customers from retail customers, so that a customer that is not a broker-dealer but enters more than 390 options orders per day (on average during a calendar month) is classified as a Professional Customer and does not receive customer execution priority.[30] The 390-order threshold is also used by Cboe EDGX Exchange, Inc. (''EDGX'') with respect to its equity market to delineate Retail Priority Orders, which receive execution priority, from other retail customers. EDGX Retail Priority Orders may only be entered on behalf of a person that does not place more than 390 equity orders per day on average during a calendar month for its own beneficial account(s).[31]

EDGX and the options exchanges apply a comparable methodology and supervisory requirements to determine whether the 390-order threshold has been reached as is proposed by IEX in this proposal.[32] IEX understands that the impetus for EDGX's and options exchanges' use of the 390-order threshold is to limit priority benefits and assist in ensuring that these benefits flow only to retail investors that are not engaged in a significant amount of trading activity akin to that of a professional.[33]

IEX believes that similarly restricting Retail orders to non-professional customers will expand the pool of market participants willing to provide contra-side liquidity to trade with Retail orders because the limitations will narrow the pool of Retail orders to those from customers who are less likely to be professional market participants. By expanding the pool of market participants willing to compete for providing price improvement to Retail orders, IEX believes that more Retail orders will be able to obtain meaningful price improvement for their orders. IEX also notes that 390 orders per day represents an order entered each minute during regular trading hours—from 9:30 a.m. eastern time to 4:00 p.m. eastern time—which IEX believes is a reasonable and not overly restrictive limitation in that it contemplates active trading but not at the level of a professional trader.[34] IEX believes that limiting the pool of customers eligible to enter Retail orders, as proposed, will incentivize additional resting liquidity seeking to trade against such Retail orders (and provide price improvement) because of their non-professional characteristics.[35] Thus, to the extent the proposed change is successful in increasing the pool of RLP and other contra-side liquidity it will benefit Retail orders by increasing execution opportunities and price improvement.

RLP Order Book Priority

IEX proposes to provide Order Book priority to RLP orders ahead of other non-displayed orders priced to execute at the Midpoint Price. Currently, IEX Rule 11.232(e)(3)(A)(iv) provides that RLP orders are prioritized after all other non-displayed orders priced to trade at the Midpoint Price. This approach was adopted by IEX originally because RLP orders were a new order type and are only eligible to trade against Retail orders. However, IEX now believes that RLP orders should have higher priority than other non-displayed orders priced to trade at the Midpoint Price in order to provide additional incentives for the entry of RLP orders and concomitant provision of price improvement to Retail orders. The Exchange notes that other exchanges that offer retail programs enable retail liquidity providing orders that provide immaterial sub-penny price improvement to achieve queue priority by providing a retail order type that trades first with retail liquidity providing orders before trading with other similarly priced orders.[36]

Thus, as proposed, IEX Rule 11.232(e)(3)(A) would be amended to provide that a Retail order to buy (sell) shall execute upon entry against sell (buy) orders resting on the Order Book in the following order:

(i) Displayed sell (buy) orders at the NBO (NBB) during a locked or crossed market;

(ii) displayed sell (buy) odd lot orders priced to trade between the NBB (NBO) and the MidPoint Price;

(iii) Retail Liquidity Provider orders priced to trade at the Midpoint Price; and

(iv) nondisplayed orders priced to trade at the Midpoint Price.

Retail Liquidity Identifier

IEX proposes to disseminate a Retail Liquidity Identifier through the Exchange's proprietary market data feeds, TOPS [37] and DEEP,[38] and the appropriate SIP when RLP order interest aggregated to form at least one round lot for a particular security is available in the System, provided that the RLP order interest is resting at the Midpoint Price and is priced at least $0.001 better than the NBB or NBO (''RLP Interest''). The purpose of the Retail Liquidity Identifier is to provide relevant market information to RMOs that there is RLP Interest on IEX, thereby incentivizing them to send Retail orders to IEX. The Exchange does not believe that such market information constitutes a ''quote'' within the meaning of Regulation NMS because it would not include a specific price or size of the interest.[39] The Retail Liquidity Identifier will reflect the symbol and the side (buy or sell) of the RLP Interest but will not include the price or size. While an explicit price will not be disseminated, because RLP orders are only eligible to trade at the Midpoint Price, dissemination will thus reflect the

[30] *See, e.g.,* Nasdaq Stock Market LLC Options 1, Section 1(a)(47); NYSE Arca, Inc. (''Arca'') Rule 6.1A–O(a)(4A).

[31] *See* EDGX Rule 11.9 Interpretations and Policies .01.

[32] *See* EDGX Rule 11.9 Interpretations and Policies .02.

[33] *See* Securities Exchange Act Release No. 87200 (October 2, 2019), 84 FR 53788, 53791 (October 8, 2019) (SR–CboeEDGX–2019–012) (order approving EDGX Retail Priority Orders); *see also* Securities Exchange Act Release No. 89991 (September 24, 2020), 85 FR 61782, 61783 (September 30, 2020) (SR–MIAX–2020–31) (giving priority to orders submitted on behalf of non-professional customers who submit less than 390 orders per day).

[34] For example, an analysis of orders sent to IEX by Members and customers conducting a proprietary trading business indicates that many of such Members and customers typically send millions of orders per day and even the less active send thousands of orders per day.

[35] This approach was supported by Citadel Securities in a comment letter on EDGX's retail priority proposal. Citadel Securities notes that ''[t]he market's experience with [retail programs] evidences the failure of an overly broad definition of 'Retail Order'. [Retail programs] have not gained traction in the market, precisely because the [retail programs'] definition of 'Retail Order' includes orders from both retail investors as well as active professional traders. To the extent that the 'Retail Order' flow routed to [retail programs] includes orders from active professional traders and is thus not as attractive to other market participants, those market participants will simply elect not to post [retail] liquidity and fill-rates for [retail] routes will be low.'' *See* Letter dated April 26, 2019 from Stephen John Berger, Citadel, to Eduardo A. Aleman, Commission.

[36] *See, e.g.,* Arca Rule 7.44–E(k) (Retail orders trade first with retail price improvement orders (akin to IEX's RLP orders), and then with all other orders to sell (buy) with a working price below (above) the NBO (NBB)); *See also* BYX Rule 11.24(f); and Nasdaq BX, Inc. (''Nasdaq BX'') Rule 4702(b)(6)(A).

[37] *See* IEX Rule 11.330(a)(1).

[38] *See* IEX Rule 11.330(a)(3).

[39] The Exchange plans to submit a letter requesting that the staff of the Division of Trading and Markets not recommend any enforcement action under Rule 602 of Regulation NMS (''Quote Rule'') based on the Exchange's and its Members' participation in the Retail Program.

availability of price improvement at the Midpoint Price. A number of other exchanges that offer retail programs also disseminate a Retail Liquidity Identifier on their proprietary market data feeds and the appropriate SIP if such interest would provide at least $0.001 of price improvement.[40] IEX's proposal is comparable, but (as discussed below) because the RLP orders will be resting at the Midpoint Price, IEX's Retail Liquidity Indicator will reflect at least $0.005 of price improvement for any orders priced at or above $1.00 per share unless the NBBO is locked or crossed. The Exchange believes that it is appropriate to limit dissemination of the Retail Liquidity Identifier to those cases when at least one round lot of RLP order interest is available in order to limit dissemination to cases in which there is a material amount of RLP trading interest available on the IEX Order Book.

As proposed, IEX would only disseminate the Retail Liquidity Identifier when the RLP order interest is resting at the Midpoint Price and is priced at least $0.001 better than the NBB or NBO, consistent with the rules of the other exchanges that disseminate Retail Liquidity Identifiers[41] as well as the SIP Plans' requirements.[42] Because RLP orders are proposed to be only midpoint peg orders, they will always represent at least $0.001 price improvement over the NBB or NBO, with two exceptions: (i) Locked or crossed markets and (ii) sub-dollar quotes when the security's spread is less than $0.002.[43] When the market is locked, under IEX Rule 11.190(h)(3)(C) the Exchange considers the Midpoint Price to be equal to the locking price and when the market is crossed, under IEX Rule 11.190(h)(3)(D) the Exchange considers the Midpoint Price to be indeterminable. In these situations, RLP orders are repriced as specified in the applicable rule provision and would not provide any price improvement to an incoming Retail order, and therefore will not comprise RLP Interest for purposes of the Retail Liquidity Indicator. Similarly, when a particular security is priced less than $1.00 per share, its MPV is $0.0001, so the Midpoint Price will not always represent at least $0.001 in price improvement.[44] Therefore, IEX will only disseminate RLP Interest for sub-dollar securities if the spread in the security is greater than or equal to $0.002, meaning the Midpoint Price represents at least $0.001 price improvement over the NBB or NBO. With respect to the requirement that an RLP order must be resting at the Midpoint Price in order to be included in the RLP Interest to be disseminated, the Exchange notes that an RLP order could have a limit price less aggressive than the Midpoint Price in which case it would not be eligible to trade with an incoming Retail order and therefore should not be included in the Retail Liquidity Identifier dissemination since it would not reflect interest available to trade with Retail orders.

RLP Order Type Definition

IEX proposes to amend the definition of RLP orders so such orders can only be midpoint peg orders, instead of Discretionary Peg orders, and cannot include a minimum quantity condition. Currently an RLP order is a Discretionary Peg order that is only eligible to execute against Retail orders through the execution process described in IEX Rule 11.232(e).

In connection with the proposed changes, described above, to disseminate a Retail Liquidity Identifier and provide enhanced priority to RLP orders, IEX believes that it is appropriate that RLP orders be midpoint peg orders. Specifically, IEX notes that midpoint peg orders post on the Order Book at the Midpoint Price while Discretionary Peg orders post on the Order Book at the less aggressive of the order's limit price or a price one minimum price variation less aggressive than the NBB or NBO (as applicable) and exercise price discretion to the Midpoint Price except during periods of quote instability when Discretionary Peg orders are not permitted to trade at a price more aggressive than their resting price.[45] Thus, disseminating a Retail Liquidity Identifier of RLP Interest at the Midpoint Price would be unnecessarily complicated if RLP orders were to continue to be Discretionary Peg orders since they do not explicitly post to the Order Book at the Midpoint Price. Additionally, IEX's rules provide that Discretionary Peg orders are prioritized behind any non-displayed interest at the discretionary price (in this case the Midpoint Price),[46] so it would be inconsistent with the priority rules for RLP Discretionary Peg orders to have priority over non-RLP midpoint peg orders that do rest at the Midpoint Price.

Similarly, permitting an RLP order to include a minimum quantity condition would reduce the determinism of the order's availability to trade at the Midpoint Price. IEX also believes that the protections that Discretionary Peg orders receive because they do not exercise price discretion to the Midpoint Price during periods of quote instability, or by utilizing a minimum quantity condition to avoid potential information leakage, are less necessary when trading against Retail orders. Moreover, IEX believes that the proposed changes will increase execution rates for Retail orders because RLP orders will not be subject to contingencies based on quote instability or minimum quantity requirements.

Implementation

If the Commission approves this proposed rule change, the Exchange will implement it within 90 days of approval and provide at least ten (10) days' notice to Members and market participants of the implementation timeline.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,[47] in general, and furthers the objectives of Section 6(b)(5),[48] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Commission has consistently emphasized that the U.S. capital markets should be structured with the interests of retail investors in mind[49] and the enhancements to the Retail Program proposed in this rule change proposal are explicitly designed with that goal in mind. The four proposed enhancements to the Retail Program are individually and collectively designed

[40] *See, e.g.,* BYX Rule 11.24(e); Nasdaq BX Rule 4780(e).

[41] *See supra* note 40.

[42] *See* January 26, 2021 CQS Participant Input Binary Specification Version 2.6a, available at *https://www.ctaplan.com/publicdocs/ctaplan/CQS_Pillar_Input_Specification.pdf* and May 2020 UTP Data Feed Services Specification Version 1.5, available at *https://www.utpplan.com/DOC/UtpBinaryOutputSpec.pdf*.

[43] The minimum price variant (''MPV'') for bids, offers, or indications of interest priced less than $1.00 per share is $0.0001. *See* IEX Rule 11.210(a)(2).

[44] For example, if a security's NBB is $0.505 and NBO is $0.506, the Midpoint Price would be $0.5055, which is $0.0005 more than the NBB and less than NBO, so it would not represent at least $0.001 price improvement over the NBB or NBO, and therefore will not comprise RLP Interest for purposes of the Retail Liquidity Indicator.

[45] *See* IEX Rule 11.190(g).

[46] *See* IEX Rule 11.220(a)(1)(C)(vii).

[47] 15 U.S.C. 78f(b).

[48] 15 U.S.C. 78f(b)(5).

[49] *See supra* note 22.

to benefit retail investors by providing enhanced opportunities for such investors to obtain meaningful price improvement. The four enhancements are designed to work in tandem to narrow the pool of market participants eligible to enter Retail orders to those who are less likely to be professional traders and thereby attract increased contra-side liquidity seeking to trade against and provide meaningful price improvement to such Retail orders, as well as to publicize when there is non-trivial contra-side price improving interest available, and fine tune the requirements applicable to such interest so that it is more deterministic.

The Exchange also believes that the proposed rule change is consistent with the protection of investors because it is designed to increase competition among execution venues by enhancing IEX's Retail Program which offers the potential for meaningful price improvement to orders of retail investors, including through incentivizing market participants to provide additional liquidity to execute against the orders of retail investors.

Specifically, the Exchange believes that limiting the use of Retail orders to only those retail investors who do not appear to be engaged in trading activity akin to that of a professional is consistent with the protection of investors and the public interest because it is designed to enable the benefits of the Retail Program to accrue to less sophisticated market participants that may be underserved by existing trading alternatives. Moreover, as discussed in the Purpose section and above, limiting the use of Retail orders in this manner is designed to incentivize additional resting liquidity seeking to trade against and provide price improvement to Retail orders.

Further, the Exchange believes that using a threshold of 390 orders per day on average during a calendar month (which is equivalent to one order per minute during the trading day) is a reasonable way to differentiate between less active retail investors and those that are more akin to market professionals. IEX believes that it is consistent with the protection of investors and the public interest to treat an investor that enters more than one order per minute as a professional trader, and notes that this threshold is used to differentiate between priority and professional customers in the options industry and by EDGX for its retail priority program. Thus, identifying Retail orders based on the average number of orders entered for a beneficial account is a familiar and objective approach to distinguish ordinary retail investors from active traders akin to professionals.[50]

The Exchange also believes that the counting methodology and additional policies and procedures that RMOs must comply with to reasonably ensure that Retail orders are appropriately represented on the Exchange are consistent with the Act. In this regard IEX notes that such methodology and policies and procedures are substantially identical to those in place at EDGX. The Exchange has a robust regulatory program, including an exam process implemented by FINRA, in place to monitor for compliance with existing RMO requirements, which will be enhanced for this proposal.

The Exchange believes that its proposal to narrow the definition of Retail order is not unfairly discriminatory but rather is designed to promote a competitive process for retail executions while providing retail investors with the potential to receive meaningful price improvement. All retail programs, including IEX's, provide for differentiation of retail orders from other orders. The proposed changes are merely incremental, designed to enhance IEX's ability to compete for retail order flow and retail liquidity and thereby provide benefits to retail investors from the better price that liquidity providers are willing to give their orders.

The Exchange also believes that providing Order Book priority to RLP orders ahead of other non-displayed orders priced to execute at the Midpoint Price is consistent with the protection of investors and the public interest because it is designed to provide additional incentives for the entry of RLP orders and concomitant provision of price improvement to Retail orders, as discussed in the Purpose section. The Exchange also notes that Retail orders will still be able to execute against other orders priced to execute at the Midpoint Price so the proposed changes is not creating a segmented liquidity pool. Additionally, the Exchange believes that providing Order Book priority to RLP orders is not unfairly discriminatory since any Member can enter an RLP order. Further, as discussed in the Purpose section, this proposed change is consistent with the approach of several other exchanges that provide immaterial sub-penny price improvement to achieve queue priority by providing a retail order type that trades first with retail liquidity providing orders before trading with other similarly priced orders.[51]

Additionally, the Exchange believes that it is consistent with the Act to disseminate a Retail Liquidity Identifier, as described in the Purpose section. The purpose of the Retail Liquidity Identifier is to provide relevant market information to RMOs that there is RLP Interest on IEX. The dissemination is thus designed to augment the total mix of information available to RMOs that may benefit Retail orders they represent. The Exchange notes that other exchanges disseminate comparable information regarding available contra-side liquidity available to execute against retail orders, as noted in the Purpose section.

Further, the Exchange believes it is consistent with the Act to amend the definition of RLP orders to make them midpoint peg orders instead of Discretionary Peg orders, so that the availability of such orders to trade at the Midpoint Price is more deterministic, as described in the Purpose section. IEX also believes that the proposed changes will benefit Retail orders to the extent that their execution rates, and resulting price improvement, increase.

The Commission consistently highlights the need to ensure that the U.S. capital markets are structured with the interests of retail investors in mind, and recently highlighted its focus on the ''long-term interest of Main Street Investors'' as its number one strategic goal for fiscal years 2018 to 2022.[52] The Exchange believes the proposed enhancements to its Retail Program will better serve the retail investing public by providing them with expanded opportunities for meaningful price improvement on eligible trades.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, IEX believes that the proposed enhancements to our Retail Program would continue to enhance competition

[50] This approach was suggested by Citadel Securities in a comment letter on the EDGX retail priority proposal which did not initially include the 390 orders per day on average limitation. In its comment letter, Citadel Securities noted that the definition of ''Retail Order'' used by various equities exchanges does not adequately distinguish retail investors' orders from those of active professional traders. Citadel went on to suggest that EDGX leverage the definition of ''professional customer'' used by various options exchanges that is defined as a trader who places ore than 390 orders in listed options per day on average during a calendar month for their own beneficial account. *See* Letter dated April 26, 2019 from Stephen John Berger, Citadel, to Eduardo A. Aleman, Commission.

[51] *See supra* note 36.

[52] *See supra* note 22.

and execution quality for retail customers.

The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition since competing venues have and can continue to adopt similar retail programs, subject to the SEC rule change process. The Exchange operates in a highly competitive market in which market participants can easily direct their orders to competing venues, including off-exchange venues.

The Exchange also does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. While orders submitted by some Members will be treated differently, as described in the Purpose section, those differences are not based on the type of Member entering orders but on whether the order is for a retail customer, and there is no restriction on whether a Member can handle retail customer orders. Further, any Member can enter an RLP order.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will: (a) By order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2021–06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2021–06. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2021–06 and should be submitted on or before May 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

J. Matthew DeLesDernier,

Assistant Secretary.

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[53] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91521; File No. SR–CboeBZX–2021–024]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing of a Proposed Rule Change to List and Trade Shares of the WisdomTree Bitcoin Trust Under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares

April 9, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on March 26, 2021, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange rule change to list and trade shares of the WisdomTree Bitcoin Trust (the ''Trust''),[3] under BZX Rule 14.11(e)(4), Commodity-Based Trust Shares. The shares of the Trust are referred to herein as the ''Shares.''

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Trust was formed as a Delaware statutory trust on March 8, 2021 and is operated as a grantor trust for U.S. federal tax purposes. The Trust has no fixed termination date.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to list and trade the Shares under BZX Rule 14.11(e)(4),[4] which governs the listing and trading of Commodity-Based Trust Shares on the Exchange.[5] WisdomTree Digital Commodity Services, LLC is the sponsor of the Trust (the ''Sponsor''). The Shares will be registered with the Commission by means of the Trust's registration statement on Form S–1 (the ''Registration Statement'').[6]

Background

Bitcoin is a digital asset based on the decentralized, open source protocol of the peer-to-peer computer network launched in 2009 that governs the creation, movement, and ownership of bitcoin and hosts the public ledger, or ''blockchain,'' on which all bitcoin transactions are recorded (the ''Bitcoin Network'' or ''Bitcoin''). The decentralized nature of the Bitcoin Network allows parties to transact directly with one another based on cryptographic proof instead of relying on a trusted third party. The protocol also lays out the rate of issuance of new bitcoin within the Bitcoin Network, a rate that is reduced by half approximately every four years with an eventual hard cap of 21 million. It's generally understood that the combination of these two features—a systemic hard cap of 21 million bitcoin and the ability to transact trustlessly with anyone connected to the Bitcoin Network—gives bitcoin its value.[7]

The first rule filing proposing to list an exchange-traded product to provide exposure to bitcoin in the U.S. was submitted by the Exchange on June 30, 2016.[8] At that time, blockchain technology, and digital assets that utilized it, were relatively new to the broader public. The market cap of all bitcoin in existence at that time was approximately $10 billion. No registered offering of digital asset securities or shares in an investment vehicle with exposure to bitcoin or any other cryptocurrency had yet been conducted, and the regulated infrastructure for conducting a digital asset securities offering had not begun to develop.[9] Similarly, regulated U.S. bitcoin futures contracts did not exist. The Commodity Futures Trading Commission (the ''CFTC'') had determined that bitcoin is a commodity,[10] but had not engaged in significant enforcement actions in the space. The New York Department of Financial Services (''NYDFS'') adopted its final BitLicense regulatory framework in 2015, but had only approved four entities to engage in activities relating to virtual currencies (whether through granting a BitLicense or a limited-purpose trust charter) as of June 30, 2016.[11] While the first over-the-counter bitcoin fund launched in 2013, public trading was limited and the fund had only $60 million in assets.[12] There were very few, if any, traditional financial institutions engaged in the space, whether through investment or providing services to digital asset companies. In January 2018, the Staff of the Commission noted in a letter to the Investment Company Institute and SIFMA that it was not aware, at that time, of a single custodian providing fund custodial services for digital assets.[13]

Fast forward to the first quarter of 2021 and the digital assets financial ecosystem, including bitcoin, has progressed significantly. The development of a regulated market for digital asset securities has significantly evolved, with market participants having conducted registered public offerings of both digital asset securities [14] and shares in investment vehicles holding bitcoin futures.[15] Additionally, licensed and regulated service providers have emerged to provide fund custodial services for digital assets, among other services. For example, in December 2020, the Commission adopted a conditional no-action position permitting certain special purpose broker-dealers to custody digital asset securities under Rule 15c3–3 under the Exchange Act; [16] in September 2020, the Staff of the Commission released a no-action letter permitting certain broker-dealers to operate a non-custodial Alternative Trading System (''ATS'') for digital asset securities, subject to specified conditions; [17] in October 2019, the Staff of the Commission granted temporary relief from the clearing agency registration requirement to an entity seeking to establish a securities clearance and settlement system based

[4] The Commission approved BZX Rule 14.11(e)(4) in Securities Exchange Act Release No. 65225 (August 30, 2011), 76 FR 55148 (September 6, 2011) (SR–BATS–2011–018).

[5] All statements and representations made in this filing regarding (a) the description of the portfolio, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules and surveillance procedures shall constitute continued listing requirements for listing the Shares on the Exchange.

[6] The Trust has filed a registration statement on Form S–1 under the Securities Act of 1933, dated March 9, 2021 (File No. 333–254134) (''Registration Statement''). The description of the Trust and the Shares contained herein are based on the Registration Statement. The Registration Statement for the Trust is not yet effective and the Shares will not trade on the Exchange until such time that the Registration Statement is effective.

[7] For additional information about bitcoin and the Bitcoin Network, *see https://bitcoin.org/en/getting-started*; *https://www.fidelitydigitalassets.com/articles/addressing-bitcoin-criticisms*; and *https://www.vaneck.com/education/investment-ideas/investing-in-bitcoin-and-digital-assets/*.

[8] *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018). This proposal was subsequently disapproved by the Commission. *See* Securities Exchange Act Release No. 83723 (July 26, 2018), 83 FR 37579 (August 1, 2018) (the ''Winklevoss Order'').

[9] Digital assets that are securities under U.S. law are referred to throughout this proposal as ''digital asset securities.'' All other digital assets, including bitcoin, are referred to interchangeably as ''cryptocurrencies'' or ''virtual currencies.'' The term ''digital assets'' refers to all digital assets, including both digital asset securities and cryptocurrencies, together.

[10] *See* ''In the Matter of Coinflip, Inc.'' (''Coinflip'') (CFTC Docket 15–29 (September 17, 2015)) (order instituting proceedings pursuant to Sections 6(c) and 6(d) of the CEA, making findings and imposing remedial sanctions), in which the CFTC stated:

''Section 1a(9) of the CEA defines 'commodity' to include, among other things, 'all services, rights, and interests in which contracts for future delivery are presently or in the future dealt in.' 7 U.S.C. 1a(9). The definition of a 'commodity' is broad. *See, e.g., Board of Trade of City of Chicago* v. *SEC,* 677 F. 2d 1137, 1142 (7th Cir. 1982). Bitcoin and other virtual currencies are encompassed in the definition and properly defined as commodities.''

[11] A list of virtual currency businesses that are entities regulated by the NYDFS is available on the NYDFS website. *See https://www.dfs.ny.gov/apps_and_licensing/virtual_currency_businesses/regulated_entities.*

[12] Data as of March 31, 2016 according to publicly available filings. *See* Bitcoin Investment Trust Form S–1, dated May 27, 2016, available: *https://www.sec.gov/Archives/edgar/data/1588489/000095012316017801/filename1.htm.*

[13] *See* letter from Dalia Blass, Director, Division of Investment Management, U.S. Securities and Exchange Commission to Paul Schott Stevens, President & CEO, Investment Company Institute and Timothy W. Cameron, Asset Management Group—Head, Securities Industry and Financial Markets Association (January 18, 2018), *available at https://www.sec.gov/divisions/investment/noaction/2018/cryptocurrency-011818.htm.*

[14] *See* Prospectus supplement filed pursuant to Rule 424(b)(1) for INX Tokens (Registration No. 333–233363), *available at: https://www.sec.gov/Archives/edgar/data/1725882/000121390020023202/ea125858-424b1_inxlimited.htm.*

[15] *See* Prospectus filed by Stone Ridge Trust VI on behalf of NYDIG Bitcoin Strategy Fund Registration, *available at: https://www.sec.gov/Archives/edgar/data/1764894/000119312519309942/d693146d497.htm.*

[16] *See* Securities Exchange Act Release No. 90788, 86 FR 11627 (February 26, 2021) (File Number S7–25–20) (Custody of Digital Asset Securities by Special Purpose Broker-Dealers).

[17] *See* letter from Elizabeth Baird, Deputy Director, Division of Trading and Markets, U.S. Securities and Exchange Commission to Kris Dailey, Vice President, Risk Oversight & Operational Regulation, Financial Industry Regulatory Authority (September 25, 2020), *available at: https://www.sec.gov/divisions/marketreg/mr-noaction/2020/finra-ats-role-in-settlement-of-digital-asset-security-trades-09252020.pdf.*

on distributed ledger technology,[18] and multiple transfer agents who provide services for digital asset securities registered with the Commission.[19]

Outside the Commission's purview, the regulatory landscape has changed significantly since 2016, and cryptocurrency markets have grown and evolved as well. The market for bitcoin is approximately 100 times larger, having recently reached a market cap of over $1 trillion. As of February 27, 2021, bitcoin's market cap is greater than companies such as Facebook, Inc., Berkshire Hathaway Inc., and JP Morgan Chase & Co. CFTC regulated bitcoin futures represented approximately $28 billion in notional trading volume on Chicago Mercantile Exchange (''CME'') (''Bitcoin Futures'') in December 2020 compared to $737 million, $1.4 billion, and $3.9 billion in total trading in December 2017, December 2018, and December 2019, respectively. Bitcoin Futures traded over $1.2 billion per day in December 2020 and represented $1.6 billion in open interest compared to $115 million in December 2019, which the Exchange believes represents a regulated market of significant size, as further discussed below.[20] The CFTC has exercised its regulatory jurisdiction in bringing a number of enforcement actions related to bitcoin and against trading platforms that offer cryptocurrency trading.[21] The U.S. Office of the Comptroller of the Currency (the ''OCC'') has made clear that federally-chartered banks are able to provide custody services for cryptocurrencies and other digital assets.[22] The OCC recently granted conditional approval of two charter conversions by state-chartered trust companies to national banks, both of which provide cryptocurrency custody services.[23] NYDFS has granted no fewer than twenty-five BitLicenses, including to established public payment companies like PayPal Holdings, Inc. and Square, Inc., and limited purpose trust charters to entities providing cryptocurrency custody services, including the custodian of the Trust (the ''Bitcoin Custodian'').[24] The U.S. Treasury Financial Crimes Enforcement Network (''FinCEN'') has released extensive guidance regarding the applicability of the Bank Secrecy Act (''BSA'') and implementing regulations to virtual currency businesses,[25] and has proposed rules imposing requirements on entities subject to the BSA that are specific to the technological context of virtual currencies.[26] In addition, the Treasury's Office of Foreign Assets Control (''OFAC'') has brought enforcement actions over apparent violations of the sanctions laws in connection with the provision of wallet management services for digital assets.[27]

In addition to the regulatory developments laid out above, more traditional financial market participants appear to be embracing cryptocurrency: Large insurance companies,[28] asset managers,[29] university endowments,[30] pension funds,[31] and even historically bitcoin skeptical fund managers [32] are allocating to bitcoin. The largest over-the-counter bitcoin fund previously filed a Form 10 registration statement, which the Staff of the Commission reviewed and which took effect automatically, and is now a reporting company.[33] Established companies like Tesla, Inc.,[34] MicroStrategy Incorporated,[35] and Square, Inc.,[36] among others, have recently announced substantial investments in bitcoin in amounts as large as $1.5 billion (Tesla) and $425 million (MicroStrategy). Suffice to say, bitcoin is on its way to gaining mainstream usage.

Despite these developments, access for U.S. retail investors to gain exposure to bitcoin via a transparent and

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[18] *See* letter from Jeffrey S. Mooney, Associate Director, Division of Trading and Markets, U.S. Securities and Exchange Commission to Charles G. Cascarilla & Daniel M. Burstein, Paxos Trust Company, LLC (October 28, 2019), *available at: https://www.sec.gov/divisions/marketreg/mr-noaction/2019/paxos-trust-company-102819-17a.pdf.*

[19] *See, e.g.,* Form TA–1/A filed by Tokensoft Transfer Agent LLC (CIK: 0001794142) on January 8, 2021, *available at: https://www.sec.gov/Archives/edgar/data/1794142/000179414219000001/xslFTA1X01/primary_doc.xml.*

[20] All statistics and charts included in this proposal are sourced from *https://www.cmegroup.com/trading/bitcoin-futures.html.*

[21] The CFTC's annual report for Fiscal Year 2020 (which ended on September 30, 2020) noted that the CFTC ''continued to aggressively prosecute misconduct involving digital assets that fit within the CEA's definition of commodity'' and ''brought a record setting seven cases involving digital assets.'' *See* CFTC FY2020 Division of Enforcement Annual Report, *available at: https://www.cftc.gov/media/5321/DOE_FY2020_AnnualReport_120120/download.* Additionally, the CFTC filed on October 1, 2020, a civil enforcement action against the owner/operators of the BitMEX trading platform, which was one of the largest bitcoin derivative exchanges. *See* CFTC Release No. 8270–20 (October 1, 2020) *available at: https://www.cftc.gov/PressRoom/PressReleases/8270-20.*

[22] *See* OCC News Release 2021–2 (January 4, 2021) *available at: https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-2.html.*

[23] *See* OCC News Release 2021–6 (January 13, 2021) *available at: https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-6.html* and OCC News Release 2021–19 (February 5, 2021) *available at: https://www.occ.gov/news-issuances/news-releases/2021/nr-occ-2021-19.html.*

[24] The Exchange notes that the Sponsor is finalizing negotiations with the Bitcoin Custodian and it will submit an amendment to this proposal upon execution of an agreement with the Bitcoin Custodian.

[25] *See* FinCEN Guidance FIN–2019–G001 (May 9, 2019) (Application of FinCEN's Regulations to Certain Business Models Involving Convertible Virtual Currencies) *available at: https://www.fincen.gov/sites/default/files/2019-05/FinCEN%20Guidance%20CVC%20FINAL%20508.pdf.*

[26] *See* U.S. Department of the Treasury Press Release: ''The Financial Crimes Enforcement Network Proposes Rule Aimed at Closing Anti-Money Laundering Regulatory Gaps for Certain Convertible Virtual Currency and Digital Asset Transactions'' (December 18, 2020), *available at: https://home.treasury.gov/news/press-releases/sm1216.*

[27] *See* U.S. Department of the Treasury Enforcement Release: ''OFAC Enters Into $98,830 Settlement with BitGo, Inc. for Apparent Violations of Multiple Sanctions Programs Related to Digital Currency Transactions'' (December 30, 2020) *available at: https://home.treasury.gov/system/files/126/20201230_bitgo.pdf.*

[28] On December 10, 2020, Massachusetts Mutual Life Insurance Company (MassMutual) announced that it had purchased $100 million in bitcoin for its general investment account. *See* MassMutual Press Release ''Institutional Bitcoin provider NYDIG announces minority stake purchase by MassMutual'' (December 10, 2020) *available at: https://www.massmutual.com/about-us/news-and-press-releases/press-releases/2020/12/institutional-bitcoin-provider-nydig-announces-minority-stake-purchase-by-massmutual.*

[29] *See e.g.,* ''BlackRock's Rick Rieder says the world's largest asset manager has 'started to dabble' in bitcoin'' (February 17, 2021) *available at: https://www.cnbc.com/2021/02/17/blackrock-has-started-to-dabble-in-bitcoin-says-rick-rieder.html* and ''Guggenheim's Scott Minerd Says Bitcoin Should Be Worth $400,000'' (December 16, 2020) *available at: https://www.bloomberg.com/news/articles/2020-12-16/guggenheim-s-scott-minerd-says-bitcoin-should-be-worth-400-000.*

[30] *See e.g.,* ''Harvard and Yale Endowments Among Those Reportedly Buying Crypto'' (January 25, 2021) *available at: https://www.bloomberg.com/news/articles/2021-01-26/harvard-and-yale-endowments-among-those-reportedly-buying-crypto.*

[31] *See e.g.,* ''Virginia Police Department Reveals Why its Pension Fund is Betting on Bitcoin'' (February 14, 2019) *available at: https://finance.yahoo.com/news/virginia-police-department-reveals-why-194558505.html.*

[32] *See e.g.,* ''Bridgewater: Our Thoughts on Bitcoin'' (January 28, 2021) *available at: https://www.bridgewater.com/research-and-insights/our-thoughts-on-bitcoin* and ''Paul Tudor Jones says he likes bitcoin even more now, rally still in the 'first inning'' (October 22, 2020) *available at: https://www.cnbc.com/2020/10/22/-paul-tudor-jones-says-he-likes-bitcoin-even-more-now-rally-still-in-the-first-inning.html.*

[33] *See* Letter from Division of Corporation Finance, Office of Real Estate & Construction to Barry E. Silbert, Chief Executive Officer, Grayscale Bitcoin Trust (January 31, 2020) *https://www.sec.gov/Archives/edgar/data/1588489/000000000020000953/filename1.pdf.*

[34] *See* Form 10–K submitted by Tesla, Inc. for the fiscal year ended December 31, 2020 at 23: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1318605/000156459021004599/tsla-10k_20201231.htm.*

[35] *See* Form 10–Q submitted by MicroStrategy Incorporated for the quarterly period ended September 30, 2020 at 8: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1050446/000156459020047995/mstr-10q_20200930.htm.*

[36] *See* Form 10–Q submitted by Square, Inc. for the quarterly period ended September 30, 2020 at 51: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1512673/000151267320000012/sq-20200930.htm.*

regulated exchange-traded vehicle remains limited. As investors and advisors increasingly utilize ETPs to manage diversified portfolios (including equities, fixed income securities, commodities, and currencies) quickly, easily, relatively inexpensively, and without having to hold directly any of the underlying assets, options for bitcoin exposure for U.S. investors remain limited to: (i) Investing in over-the-counter bitcoin funds (''OTC Bitcoin Funds'') that are subject to high premium/discount volatility (and high management fees) to the advantage of more sophisticated investors that are able to create and redeem shares at net asset value (''NAV'') directly with the issuing trust; (ii) facing the technical risk, complexity and generally high fees associated with buying spot bitcoin; or (iii) purchasing shares of operating companies that they believe will provide proxy exposure to bitcoin with limited disclosure about the associated risks. Meanwhile, investors in many other countries, including Canada,[37] are able to use more traditional exchange listed and traded products to gain exposure to bitcoin, disadvantaging U.S. investors and leaving them with riskier and more expensive means of getting bitcoin exposure.[38]

OTC Bitcoin Funds and Investor Protection

Over the past year, U.S. investor exposure to bitcoin through OTC Bitcoin Funds has grown into the tens of billions of dollars. With that growth, so too has grown the potential risk to U.S. investors. As described below, premium and discount volatility, high fees, insufficient disclosures, and technical hurdles are putting U.S. investor money at risk on a daily basis that could potentially be eliminated through access to a bitcoin ETP. The Exchange understands the Commission's previous focus on potential manipulation of a bitcoin ETP in prior disapproval orders, but now believes that such concerns have been sufficiently mitigated and that the growing and quantifiable investor protection concerns should be the central consideration as the Commission reviews this proposal. As such, the Exchange believes that approving this proposal (and comparable proposals submitted hereafter) provides the Commission with the opportunity to allow U.S. investors with access to bitcoin in a regulated and transparent exchange-traded vehicle that would act to limit risk to U.S. investors by: (i) Reducing premium and discount volatility; (ii) reducing management fees through meaningful competition; (iii) reducing risks associated with investing in operating companies that are imperfect proxies for bitcoin exposure; and (iv) providing an alternative to custodying spot bitcoin.

(i) OTC Bitcoin Funds and Premium/Discount Volatility

OTC Bitcoin Funds are generally designed to provide exposure to bitcoin in a manner similar to the Shares. However, unlike the Shares, OTC Bitcoin Funds are unable to freely offer creation and redemption in a way that incentivizes market participants to keep their shares trading in line with their NAV[39] and, as such, frequently trade at a price that is out of line with the value of their assets held. Historically, OTC Bitcoin Funds have traded at a significant premium to NAV.[40]

Trading at a premium or a discount is not unique to OTC Bitcoin Funds and is not in itself problematic, but the size of such premiums/discounts and volatility thereof highlight the key differences in operations and market structure of OTC Bitcoin Funds as compared to ETPs. This, combined with the significant increase in AUM for OTC Bitcoin Funds over the past year, has given rise to significant and quantifiable investor protection issues, as further described below. In fact, the largest OTC Bitcoin Fund has grown to $35.0 billion in AUM[41] and has historically traded at a premium of between roughly five and forty percent, though it has seen premiums at times above one hundred percent.[42] Recently, however, it has traded at a discount. As of March 24, 2021, the discount was approximately 14%,[43] representing around $4.9 billion in market value less than the bitcoin actually held by the fund. If premium/discount numbers move back to the middle of its historical range to a 20% premium (which historically could occur at any time and overnight), it would represent a swing of approximately $11.9 billion in value unrelated to the value of bitcoin held by the fund and if the premium returns to the upper end of its typical range, that number increases to $18.9 billion. These numbers are only associated with a single OTC Bitcoin Fund—as more and more OTC Bitcoin Funds come to market and more investor assets flood into them to get access to bitcoin exposure, the potential dollars at risk will only increase.

This raises significant investor protection issues in several ways. First, the most obvious issue is that investors are buying shares of a fund for a price that is not reflective of the per share value of the fund's underlying assets. Even operating within the normal premium range, it's possible for an investor to buy shares of an OTC Bitcoin Fund only to have those shares quickly lose 10% or more in dollar value excluding any movement of the price of bitcoin. That is to say—the price of bitcoin could have stayed exactly the same from market close on one day to market open the next, yet the value of the shares held by the investor decreased only because of the fluctuation of the premium/discount. As

[37] The Exchange notes that the Purpose Bitcoin ETF, a retail physical bitcoin ETP recently launched in Canada, reportedly reached $421.8 million in assets under management (''AUM'') in two days, demonstrating the demand for a North American market listed bitcoin exchange-traded product (''ETP''). The Purpose Bitcoin ETF also offers a class of units that is U.S. dollar denominated, which could appeal to U.S. investors. Without an approved bitcoin ETP in the U.S. as a viable alternative, U.S. investors could seek to purchase these shares in order to get access to bitcoin exposure. Given the separate regulatory regime and the potential difficulties associated with any international litigation, such an arrangement would create more risk exposure for U.S. investors than they would otherwise have with a U.S. exchange listed ETP.

[38] The Exchange notes that securities regulators in a number of other countries have either approved or otherwise allowed the listing and trading of bitcoin ETPs. Specifically, these funds include the Purpose Bitcoin ETF, Bitcoin ETF, VanEck Vectors Bitcoin ETN, WisdomTree Bitcoin ETP, Bitcoin Tracker One, BTCetc bitcoin ETP, Amun Bitcoin ETP, Amun Bitcoin Suisse ETP, 21Shares Short Bitcoin ETP, CoinShares Physical Bitcoin ETP.

[39] Because OTC Bitcoin Funds are not listed on an exchange, they are also not subject to the same transparency and regulatory oversight by a listing exchange as the Shares would be. In the case of the Trust, the existence of a surveillance-sharing agreement between the Exchange and the Bitcoin Futures market results in increased investor protections compared to OTC Bitcoin Funds.

[40] The inability to trade in line with NAV may at some point result in OTC Bitcoin Funds trading at a discount to their NAV, which has occurred more recently with respect to one prominent OTC Bitcoin Fund. While that has not historically been the case, and it is not clear whether such discounts will continue, such a prolonged, significant discount scenario would give rise to nearly identical potential issues related to trading at a premium.

[41] As of February 19, 2021. Compare to an AUM of approximately $2.6 billion on February 26, 2020, the date on which the Commission issued the most recent disapproval order for a bitcoin ETP. *See* Securities Exchange Act Release No. 88284 (February 26, 2020), 85 FR 12595 (March 3, 2020) (SR–NYSEArca–2019–39) (the ''Wilshire Phoenix Disapproval''). While the price of one bitcoin has increased approximately 400% in the intervening period, the total AUM has increased by approximately 1240%, indicating that the increase in AUM was created beyond just price appreciation in bitcoin.

[42] *See* ''Traders Piling Into Overvalued Crypto Funds Risk a Painful Exit'' (February 4, 2021) *available at: https://www.bloomberg.com/news/articles/2021-02-04/bitcoin-one-big-risk-when-investing-in-crypto-funds.*

[43] This is compared to another OTC Bitcoin Product which had a premium of over 60% on the same day, with a premium of over 200% a few days earlier.

more investment vehicles, including mutual funds and ETFs, seek to gain exposure to bitcoin, the easiest option for a buy and hold strategy is often an OTC Bitcoin Fund, meaning that even investors that do not directly buy OTC Bitcoin Funds can be disadvantaged by extreme premiums (or discounts) and premium volatility.

The second issue is related to the first and explains how the premium in OTC Bitcoin Funds essentially creates a direct payment from retail investors to more sophisticated investors. Generally speaking, only accredited investors are able to create or redeem shares with the issuing trust, which means that they are able to buy or sell shares directly with the trust at NAV (in exchange for either cash or bitcoin) without having to pay the premium or sell into the discount. While there are often minimum holding periods for shares, an investor that is allowed to interact directly with the trust is able to hedge their bitcoin exposure as needed to satisfy the holding requirements and collect on the premium or discount opportunity.

As noted above, the existence of a premium or discount and the premium/discount collection opportunity is not unique to OTC Bitcoin Funds and does not in itself warrant the approval of an exchange traded product.[44] What makes this situation unique is that such significant and persistent premiums and discounts can exist in a product with $35 billion in assets under management,[45] that billions of retail investor dollars are constantly under threat of premium/discount volatility,[46] and that premium/discount volatility is generally captured by more sophisticated investors on a riskless basis. The Exchange understands the Commission's focus on potential manipulation of a bitcoin ETP in prior disapproval orders, but now believes that current circumstances warrant that this direct, quantifiable investor protection issue should be the central consideration as the Commission determines whether to approve this proposal, particularly when the Trust as a bitcoin ETP is designed to reduce the likelihood of significant and prolonged premiums and discounts with its open-ended nature as well as the ability of market participants (*i.e.,* market makers and authorized participants) to create and redeem on a daily basis.

(ii) Spot and Proxy Exposure

Exposure to bitcoin through an ETP also presents certain advantages for retail investors compared to buying spot bitcoin directly. The most notable advantage is the use of the Bitcoin Custodian to custody the Trust's bitcoin assets. The Sponsor has carefully selected the Bitcoin Custodian, a third-party custodian that carries insurance covering both hot and cold storage and is chartered as a trust company under the New York Banking Law,[47] due to its manner of holding the Trust's bitcoin. This includes, among others, the use of ''cold'' (offline) storage to hold private keys and the employment by the Bitcoin Custodian of a certain degree of cybersecurity measures and operational best practices.[48] By contrast, an individual retail investor holding bitcoin through a cryptocurrency exchange lacks these protections. Typically, retail exchanges hold most, if not all, retail investors' bitcoin in ''hot'' (internet-connected) storage and do not make any commitments to indemnify retail investors or to observe any particular cybersecurity standard. Meanwhile, a retail investor holding spot bitcoin directly in a self-hosted wallet may suffer from inexperience in private key management (*e.g.,* insufficient password protection, lost key, etc.), which could cause them to lose some or all of their bitcoin holdings. In the Bitcoin Custodian, the Trust has engaged a regulated and licensed entity highly experienced in bitcoin custody, with dedicated, trained employees and procedures to manage the private keys to the Trust's bitcoin, and which is accountable for failures. In addition, retail investors will be able to hold the Shares in traditional brokerage accounts which provide SIPC protection if a brokerage firm fails. Thus, with respect to custody of the Trust's bitcoin assets, the Trust presents advantages from an investment protection standpoint for retail investors compared to owning spot bitcoin directly.

Finally, as described in the Background section above, recently a number of operating companies engaged in unrelated businesses—such as Tesla (a car manufacturer) and MicroStrategy (an enterprise software company)—have announced investments as large as $1.5 billion in bitcoin.[49] Without access to bitcoin exchange-traded products, retail investors seeking investment exposure to bitcoin may end up purchasing shares in these companies in order to gain the exposure to bitcoin that they seek.[50] In fact, mainstream financial news networks have written a number of articles providing investors with guidance for obtaining bitcoin exposure through publicly traded companies (such as MicroStrategy, Tesla, and bitcoin mining companies, among others) instead of dealing with the complications associated with buying spot bitcoin in the absence of a bitcoin ETP.[51] Such operating companies, however, are imperfect bitcoin proxies and provide investors with partial bitcoin exposure paired with a host of additional risks associated with whichever operating company they decide to purchase. Additionally, the disclosures provided by the aforementioned operating companies

[44] The Exchange notes, for example, that similar premiums/discounts and premium/discount volatility exist for other non-bitcoin cryptocurrency related over-the-counter funds, but that the size and investor interest in those funds does not give rise to the same investor protection concerns that exist for OTC Bitcoin Funds.

[45] At $35 billion in AUM, the largest OTC Bitcoin Fund would be the 32nd largest out of roughly 2,400 U.S. listed ETPs.

[46] The Exchange notes that in two recent incidents, the premium dropped from 28.28% to 12.29% from the close on 3/19/20 to the close on 3/20/20 and from 38.40% to 21.05% from the close on 5/13/19 to the close on 5/14/19. Similarly, over the period of 12/21/20 to 1/21/20, the premium went from 40.18% to 2.79%. While the price of bitcoin appreciated significantly during this period and NAV per share increased by 41.25%, the price per share increased by only 3.58%.

[47] New York state trust companies are subject to rigorous oversight similar to other types of entities, such as nationally chartered banking entities, that hold customer assets. Like national banks, they must obtain specific approval of their primary regulator for the exercise of their fiduciary powers. Moreover, limited purpose trust companies engaged in the custody of digital assets are subject to even more stringent requirements than national banks which, following initial approval of trust powers, generally can exercise those powers broadly without further approval of the OCC. In contrast, NYDFS requires in their approval orders that limited purpose trust companies obtain separate approval for all material changes in business.

[48] In addition to enforcing specific regulatory reporting requirements, NYDFS consistently exercises its broad authority to examine trust companies for compliance with law, risk management and general safety and soundness considerations, including to assess items such as the internal controls, client records and segregation of assets topics that are typically important to the ability of an entity to act as a qualified custodian. In this regard, the Bitcoin Custodian is subject to annual examination, with specific attention to its internal controls and risk management systems.

[49] It's been announced that MicroStrategy is currently contemplating a $600 million convertible note offering for the purpose of acquiring bitcoin. *See: https://www.cnbc.com/2021/02/16/microstrategy-shares-rise-after-revealing-plans-to-buy-more-bitcoin.html.*

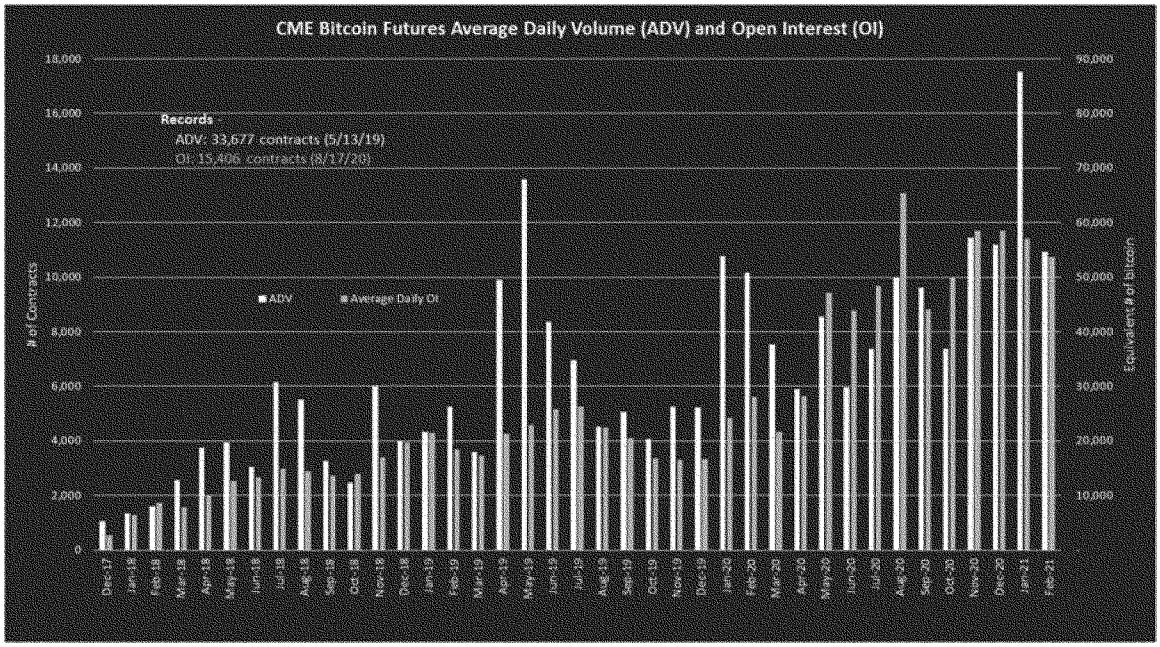
[50] In August 2017, the Commission's Office of Investor Education and Advocacy warned investors about situations where companies were publicly announcing events relating to digital coins or tokens in an effort to affect the price of the company's publicly traded common stock. *See https://www.sec.gov/oiea/investor-alerts-and-bulletins/ia_icorelatedclaims.*

[51] *See e.g.,* ''7 public companies with exposure to bitcoin'' (February 8, 2021) available at: *https://finance.yahoo.com/news/7-public-companies-with-exposure-to-bitcoin-154201525.html*; and ''Want to get in the crypto trade without holding bitcoin yourself? Here are some investing ideas'' (February 19, 2021) *available at: https://www.cnbc.com/2021/02/19/ways-to-invest-in-bitcoin-without-holding-the-cryptocurrency-yourself-.html.*

with respect to risks relating to their bitcoin holdings are generally substantially smaller than the registration statement of a bitcoin ETP, including the Registration Statement, typically amounting to a few sentences of narrative description and a handful of risk factors.[52] In other words, investors seeking bitcoin exposure through publicly traded companies are gaining only partial exposure to bitcoin and are not fully benefitting from the risk disclosures and associated investor protections that come from the securities registration process.

Bitcoin Futures

CME began offering trading in Bitcoin Futures in 2017. Each contract represents five bitcoin and is based on the CME CF Bitcoin Reference Rate.[53] The contracts trade and settle like other cash-settled commodity futures contracts. Nearly every measurable metric related to Bitcoin Futures has trended consistently up since launch and/or accelerated upward in the past year. For example, there was approximately $28 billion in trading in Bitcoin Futures in December 2020 compared to $737 million, $1.4 billion, and $3.9 billion in total trading in December 2017, December 2018, and December 2019, respectively. Bitcoin Futures traded over $1.2 billion per day on the CME in December 2020 and represented $1.6 billion in open interest compared to $115 million in December 2019. This general upward trend in trading volume and open interest is captured in the following chart.

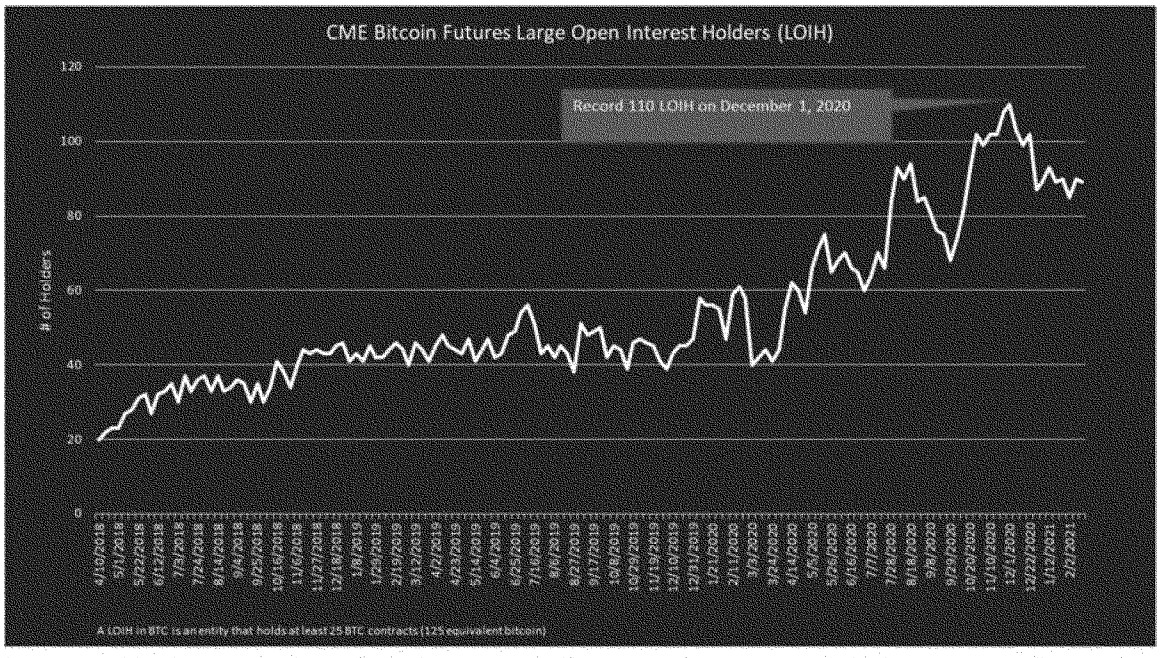


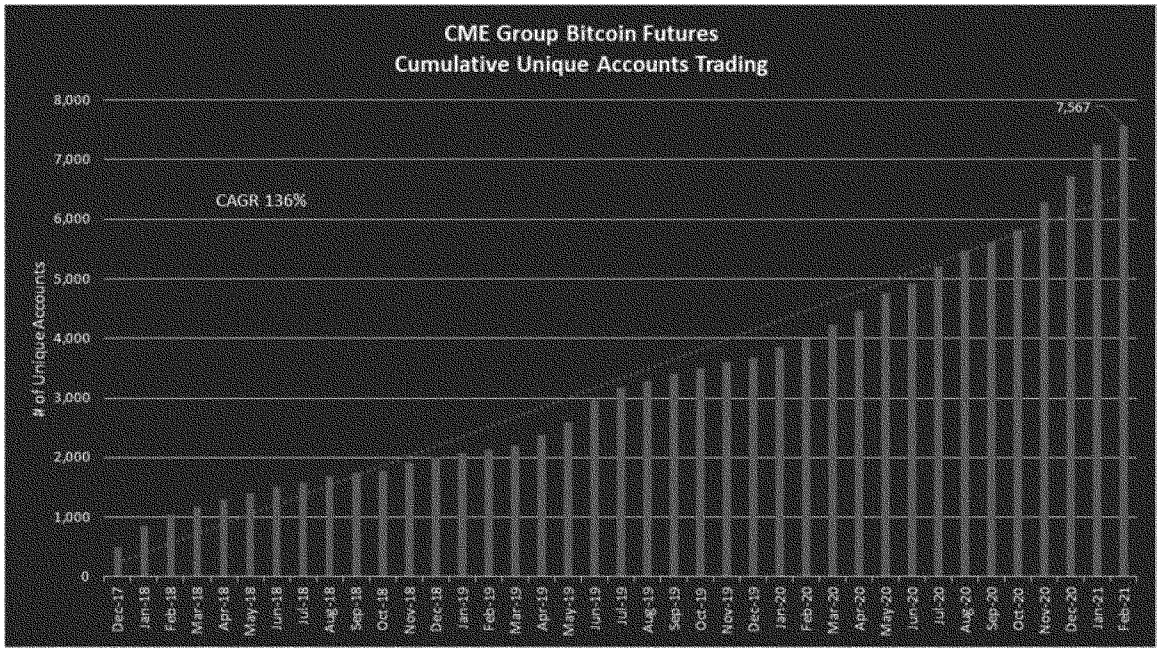
Similarly, the number of large open interest holders [54] has continued to increase even as the price of bitcoin has risen, as have the number of unique accounts trading Bitcoin Futures.

[52] *See, e.g.,* Tesla 10–K for the year ended December 31, 2020, which mentions bitcoin just nine times: *https://www.sec.gov/ix?doc=/Archives/edgar/data/1318605/000156459021004599/tsla-10k_20201231.htm.*

[53] According to CME, the CME CF Bitcoin Reference Rate aggregates the trade flow of major bitcoin spot exchanges during a specific calculation window into a once-a-day reference rate of the U.S. dollar price of bitcoin. Calculation rules are geared toward maximum transparency and real-time replicability in underlying spot markets, including Bitstamp, Coinbase, Gemini, itBit, and Kraken. For additional information, refer to *https://www.cmegroup.com/trading/cryptocurrency-indices/cf-bitcoin-reference-rate.html?redirect=/trading/cf-bitcoin-reference-rate.html.*

[54] A large open interest holder in Bitcoin Futures is an entity that holds at least 25 contracts, which is the equivalent of 125 bitcoin. At a price of approximately $30,000 per bitcoin on 12/31/20, more than 80 firms had outstanding positions of greater than $3.8 million in Bitcoin Futures.





The Sponsor further believes that academic research corroborates the overall trend outlined above and supports the thesis that the Bitcoin Futures pricing leads the spot market and, thus, a person attempting to manipulate the Shares would also have to trade on that market to manipulate the ETP. Specifically, the Sponsor believes that such research indicates that bitcoin futures lead the bitcoin spot market in price formation.[55]

[55] *See* Hu, Y., Hou, Y. and Oxley, L. (2019). ''What role do futures markets play in Bitcoin pricing? Causality, cointegration and price discovery from a time-varying perspective'' (available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7481826/*). This academic research paper concludes that ''There exist no episodes where the Bitcoin spot markets dominates the price discovery processes with regard to Bitcoin futures. This points to a conclusion that the price formation originates solely in the Bitcoin futures market. We can, therefore, conclude that the Bitcoin futures markets dominate the dynamic price discovery process based upon time-varying information share measures. Overall, price discovery seems to occur in the Bitcoin futures markets rather than the underlying spot market based upon a time-varying perspective.''

Section 6(b)(5) and the Applicable Standards

The Commission has approved numerous series of Trust Issued

Receipts,[56] including Commodity-Based Trust Shares,[57] to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) The requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices; [58] and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest. The Exchange believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that it has sufficiently demonstrated that, on the whole, the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal. Specifically, the Exchange lays out below why it believes that the significant increase in trading volume in Bitcoin Futures, the growth of liquidity at the inside in the spot market for bitcoin, and certain features of the Shares and the Reference Rate (as defined below) mitigate potential manipulation concerns to the point that the investor protection issues that have arisen from the rapid growth of over-the-counter bitcoin funds since the Commission last reviewed an exchange proposal to list and trade a bitcoin ETP, including premium/discount volatility and management fees, should be the central consideration as the Commission determines whether to approve this proposal.

(i) Designed To Prevent Fraudulent and Manipulative Acts and Practices

In order to meet this standard in a proposal to list and trade a series of Commodity-Based Trust Shares, the Commission requires that an exchange demonstrate that there is a comprehensive surveillance-sharing agreement in place [59] with a regulated market of significant size. Both the Exchange and CME are members of the Intermarket Surveillance Group (the ''ISG'').[60] The only remaining issue to be addressed is whether the Bitcoin Futures market constitutes a market of significant size, which the Exchange believes that it does. The terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which: (a) There is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct; and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[61]

The Commission has also recognized that the ''regulated market of significant size'' standard is not the only means for satisfying Section 6(b)(5) of the act, specifically providing that a listing exchange could demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[62]

(a) Manipulation of the ETP

The significant growth in Bitcoin Futures across each of trading volumes, open interest, large open interest holders, and total market participants since the Wilshire Phoenix Disapproval was issued are reflective of that market's growing influence on the spot price, which according to the academic research cited above, was already leading the spot price in 2018 and 2019. Where Bitcoin Futures lead the price in the spot market such that a potential manipulator of the bitcoin spot market (beyond just the constituents of the Reference Rate [63]) would have to participate in the Bitcoin Futures market, it follows that a potential manipulator of the Shares would similarly have to transact in the Bitcoin Futures market because the Reference Rate is based on spot prices. Further, the Trust only allows for in-kind creation and redemption, which, as further described below, reduces the potential for manipulation of the Shares through manipulation of the Reference Rate or any of its individual constituents, again emphasizing that a potential manipulator of the Shares would have to manipulate the entirety of the bitcoin spot market, which is led by the Bitcoin Futures market. As such, the Exchange believes that part (a) of the significant market test outlined above is satisfied and that common membership in ISG between the Exchange and CME would assist the listing exchange in detecting and deterring misconduct in the Shares.

(b) Predominant Influence on Prices in Spot and Bitcoin Futures

The Exchange also believes that trading in the Shares would not be the predominant force on prices in the

[56] *See* Exchange Rule 14.11(f).

[57] Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

[58] As the Exchange has stated in a number of other public documents, it continues to believe that bitcoin is resistant to price manipulation and that ''other means to prevent fraudulent and manipulative acts and practices'' exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of bitcoin trading render it difficult and prohibitively costly to manipulate the price of bitcoin. The fragmentation across bitcoin platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity challenging. To the extent that there are bitcoin exchanges engaged in or allowing wash trading or other activity intended to manipulate the price of bitcoin on other markets, such pricing does not normally impact prices on other exchange because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin price on any single venue would require manipulation of the global bitcoin price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular bitcoin exchange or OTC platform. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences.

[59] As previously articulated by the Commission, ''The standard requires such surveillance-sharing agreements since ''they provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance- sharing agreement with markets trading underlying securities for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules. The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.'' The Commission has historically held that joint membership in ISG constitutes such a surveillance sharing agreement. *See* Wilshire Phoenix Disapproval.

[60] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[61] *See* Wilshire Phoenix Disapproval.

[62] *See* Winklevoss Order at 37580. The Commission has also specifically noted that it ''is not applying a ''cannot be manipulated'' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met. *Id.* at 37582.

[63] As further described below, the Reference Rate for the Fund is based on materially the same methodology (except calculation time) as the Administrator's BRR, which is the rate on which bitcoin futures contracts are cash-settled in U.S. dollars at the CME.

Bitcoin Futures market (or spot market) for a number of reasons, including the significant volume in the Bitcoin Futures market, the size of bitcoin's market cap (approximately $1 trillion), and the significant liquidity available in the spot market. In addition to the Bitcoin Futures market data points cited above, the spot market for bitcoin is also very liquid. According to data from CoinRoutes from February 2021, the cost to buy or sell $5 million worth of bitcoin averages roughly 10 basis points with a market impact of 30 basis points.[64] For a $10 million market order, the cost to buy or sell is roughly 20 basis points with a market impact of 50 basis points. Stated another way, a market participant could enter a market buy or sell order for $10 million of bitcoin and only move the market 0.5%. More strategic purchases or sales (such as using limit orders and executing through OTC bitcoin trade desks) would likely have less obvious impact on the market—which is consistent with MicroStrategy, Tesla, and Square being able to collectively purchase billions of dollars in bitcoin. As such, the combination of Bitcoin Futures leading price discovery, the overall size of the bitcoin market, and the ability for market participants, including authorized participants creating and redeeming in-kind with the Trust, to buy or sell large amounts of bitcoin without significant market impact will help prevent the Shares from becoming the predominant force on pricing in either the bitcoin spot or Bitcoin Futures markets, satisfying part (b) of the test outlined above.

(c) Other Means To Prevent Fraudulent and Manipulative Acts and Practices

As noted above, the Commission also permits a listing exchange to demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Exchange believes that such conditions are present. Specifically, the significant liquidity in the spot market and the impact of market orders on the overall price of bitcoin mean that attempting to move the price of bitcoin is costly and has grown more expensive over the past year. In January 2020, for example, the cost to buy or sell $5 million worth of bitcoin averaged roughly 30 basis points (compared to 10 basis points in 2/2021) with a market impact of 50 basis points (compared to 30 basis points in 2/2021).[65] For a $10 million market order, the cost to buy or sell was roughly 50 basis points (compared to 20 basis points in 2/2021) with a market impact of 80 basis points (compared to 50 basis points in 2/2021). As the liquidity in the bitcoin spot market increases, it follows that the impact of $5 million and $10 million orders will continue to decrease the overall impact in spot price.

Additionally, offering only in-kind creation and redemption will provide unique protections against potential attempts to manipulate the Shares. While the Sponsor believes that the Reference Rate which it uses to value the Trust's bitcoin is itself resistant to manipulation based on the methodology further described below, the fact that creations and redemptions are only available in-kind makes the manipulability of the Reference Rate significantly less important. Specifically, because the Trust will not accept cash to buy bitcoin in order to create new shares or, barring a forced redemption of the Trust or under other extraordinary circumstances, be forced to sell bitcoin to pay cash for redeemed shares, the price that the Sponsor uses to value the Trust's bitcoin is not particularly important.[66] When authorized participants are creating with the Trust, they need to deliver a certain number of bitcoin per share (regardless of the valuation used) and when they're redeeming, they can similarly expect to receive a certain number of bitcoin per share. As such, even if the price used to value the Trust's bitcoin is manipulated (which the Sponsor believes that the independent Reference Rate methodology is resistant to), the ratio of bitcoin per Share does not change and the Trust will either accept (for creations) or distribute (for redemptions) the same number of bitcoin regardless of the value. This not only mitigates the risk associated with potential manipulation, but also discourages and disincentivizes manipulation of the Reference Rate because there is little financial incentive to do so.

WisdomTree Bitcoin Trust

Delaware Trust Company is the trustee (''Trustee''). The Sponsor is responsible for the creation of the Trust and is responsible for the ongoing registration of the Shares for their public offering in the United States and the listing of Shares on the Exchange. In addition, the Sponsor: (i) Selects the Trustee, administrator, transfer Agent, Bitcoin Custodian, marketing agent and Trust auditor; (ii) negotiates various agreements and fees; and (iii) performs such other services as the Sponsor believes that the Trust may from time to time require. A third-party administrator, transfer agent, and marketing agent will be responsible for the operation and administration of the Trust, for the issuance and redemption of Shares of the Trust, and for reviewing and approving marketing materials prepared by the Trust, respectively.[67] The Sponsor provides assistance in the marketing of the Shares. The Bitcoin Custodian will be a third-party regulated custodian and will be responsible for custody of the Trust's bitcoin.[68]

According to the Registration Statement, each Share will represent a fractional undivided beneficial interest in and ownership of the Trust. The Trust's assets will consist of bitcoin held by the Bitcoin Custodian on behalf of the Trust. The Trust generally does not intend to hold cash or cash equivalents. However, there may be situations where the Trust will unexpectedly hold cash on a temporary basis.

According to the Registration Statement, the Trust is neither an investment company registered under the Investment Company Act of 1940, as amended,[69] nor a commodity pool for purposes of the Commodity Exchange Act (''CEA''), and neither the Trust nor the Sponsor is subject to regulation as a commodity pool operator or a commodity trading adviser in connection with the Shares.

When the Trust sells or redeems its Shares, it will do so in ''in-kind'' transactions in large blocks of aggregations of Shares (a ''Creation Basket''). Authorized participants will

[64] These statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021.

[65] These statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021.

[66] While the Reference Rate will not be particularly important for the creation and redemption process, it will be used for calculating fees.

[67] The Exchange notes that the Sponsor is finalizing negotiations with the administrator, transfer agent, and marketing agent and it will submit an amendment to this proposal upon execution of an agreement with the administrator, transfer agent, and marketing agent.

[68] The Exchange notes that the Sponsor is finalizing negotiations with the Bitcoin Custodian and it will submit an amendment to this proposal upon execution of an agreement with the Bitcoin Custodian.

[69] 15 U.S.C. 80a–1.

deliver, or facilitate the delivery of, bitcoin to the Trust's account with the Bitcoin Custodian in exchange for Shares when they purchase Shares, and the Trust, through the Bitcoin Custodian, will deliver bitcoin to such authorized participants when they redeem Shares with the Trust. Authorized participants may then offer Shares to the public at prices that depend on various factors, including the supply and demand for Shares, the value of the Trust's assets, and market conditions at the time of a transaction. Shareholders who buy or sell Shares during the day from their broker may do so at a premium or discount relative to the NAV of the Shares of the Trust.

Investment Objective

According to the Registration Statement and as further described below, the investment objective of the Trust is to gain exposure to the price of bitcoin, less expenses and liabilities of the Trust's operation. In seeking to achieve its investment objective, the Trust will hold bitcoin and value its Shares daily based on the value of bitcoin as reflected by the CF Bitcoin US Settlement Price (the ''Reference Rate''), which is an independently calculated value based on an aggregation of executed trade flow of major bitcoin spot exchanges. The Trust will process all creations and redemptions in-kind in transactions with authorized participants. The Trust is not actively managed.

The Reference Rate

As described in the Registration Statement, the Fund will use the Reference Rate to calculate the Trust's NAV. The Reference Rate is not affiliated with the Sponsor and was created and is administered by CF Benchmarks Ltd. (the ''Benchmark Administrator''), an independent entity, to facilitate financial products based on bitcoin. The Reference Rate is designed based on the IOSCO Principals for Financial Benchmarks and serves as a once-a-day benchmark rate of the U.S. dollar price of bitcoin (USD/BTC), calculated as of 4 p.m. Eastern time. The Reference Rate is based on materially the same methodology (except calculation time) [70] as the Benchmark Administrator's CME CF Bitcoin Reference Rate (''BRR''), which was first introduced on November 14, 2016 and is the rate on which bitcoin futures contracts are cash-settled in U.S. dollars at the CME. The Reference Rate aggregates the trade flow of several bitcoin exchanges, during an observation window between 3:00 p.m. and 4:00 p.m. Eastern time into the U.S. dollar price of one bitcoin at 4:00 p.m. Eastern time. The current constituent bitcoin exchanges of the Reference Rate are Bitstamp, Coinbase, Gemini, itBit and Kraken (the ''Constituent Bitcoin Exchanges'').

The Reference Rate is calculated based on the ''Relevant Transactions'' [71] of all of its Constituent Bitcoin Exchanges, as follows:

- All Relevant Transactions are added to a joint list, recording the time of execution, trade price and size for each transaction.
- The list is partitioned by timestamp into 12 equally-sized time intervals of 5 (five) minute length.
- For each partition separately, the volume-weighted median trade price is calculated from the trade prices and sizes of all Relevant Transactions, *i.e.,* across all Constituent Bitcoin Exchanges. A volume-weighted median differs from a standard median in that a weighting factor, in this case trade size, is factored into the calculation.
- The Reference Rate is then determined by the arithmetic mean of the volume-weighted medians of all partitions.

By employing the foregoing steps, the Reference Rate thereby seeks to ensure that transactions in bitcoin conducted at outlying prices do not have an undue effect on the value of a specific partition, large trades or clusters of trades transacted over a short period of time will not have an undue influence on the index level, and the effect of large trades at prices that deviate from the prevailing price are mitigated from having an undue influence on the benchmark level. In addition, the Sponsor notes that an oversight function is implemented by the Benchmark Administrator in seeking to ensure that the Reference Rate is administered through codified policies for Reference Rate integrity.

Availability of Information

In addition to the price transparency of the Reference Rate, the Trust will provide information regarding the Trust's bitcoin holdings as well as additional data regarding the Trust. The Trust will provide an Intraday Indicative Value (''IIV'') per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's bitcoin holdings during the trading day.

The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the BZX Official Closing Price [72] in relation to the NAV as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Official Closing Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's website. The price of bitcoin will be made available by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours. Information about the Reference Rate, including key elements of how the Reference Rate is calculated, will be publicly available at *https://www.cfbenchmarks.com.*

The NAV for the Trust will be calculated by the administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the Consolidated Tape Association (''CTA'').

[70] The Reference Rate is calculated as of 4 p.m. Eastern Time, whereas the BRR is calculated as of 4 p.m. London Time.

[71] A ''Relevant Transaction'' is any cryptocurrency versus U.S. dollar spot trade that occurs during the observation window between 3:00 p.m. and 4:00 p.m. Eastern time on a Constituent Bitcoin Exchange in the BTC/USD pair that is reported and disseminated by a Constituent Bitcoin Exchange through its publicly available API and observed by the Benchmark Administrator, CF Benchmarks Ltd.

[72] As defined in Rule 11.23(a)(3), the term ''BZX Official Closing Price'' shall mean the price disseminated to the consolidated tape as the market center closing trade.

Quotation and last sale information for bitcoin is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters, as well as the Reference Rate. Information relating to trading, including price and volume information, in bitcoin is available from major market data vendors and from the exchanges on which bitcoin are traded. Depth of book information is also available from bitcoin exchanges. The normal trading hours for bitcoin exchanges are 24 hours per day, 365 days per year.

Net Asset Value

NAV means the total assets of the Trust including, but not limited to, all bitcoin cash or other assets, less total liabilities of the Trust, each determined on the basis of generally accepted accounting principles. In determining the Trust's NAV, the administrator values the bitcoin held by the Trust based on the price set by the Reference Rate as of 4:00 p.m. Eastern Time. The administrator will determine the NAV of the Trust on each day that the Exchange is open for regular trading. The NAV for a normal trading day will be released after 4:00 p.m. Eastern Time. However, NAVs are not officially struck until later in the day (often by 5:30 p.m. Eastern Time and almost always by 8:00 p.m. Eastern Time). The pause between 4:00 p.m. Eastern Time and 5:30 p.m. Eastern Time (or later) provides an opportunity for the Trust, Benchmark Administrator or administrator to detect, flag, investigate, and correct unusual pricing should it occur. The Sponsor anticipates that the Reference Rate will be reflective of a reasonable valuation of the average spot price of bitcoin. However, in the event the Reference Rate was not available or determined by the Sponsor to not be reliable, the Sponsor would ''fair value'' the Trust's bitcoin holdings. The Sponsor does not anticipate that the need to ''fair value'' bitcoin will be a common occurrence. The Sponsor will publish the NAV and NAV per Share at *www.wisdomtree.com* as soon as practicable after their determination and availability.

Creation and Redemption of Shares

According to the Registration Statement, on any business day, an authorized participant may place an order to create one or more baskets. Purchase orders must be placed by 4:00 p.m. Eastern Time, or the close of regular trading on the Exchange, whichever is earlier. The day on which an order is received is considered the purchase order date. The total deposit of bitcoin required is an amount of bitcoin that is in the same proportion to the total assets of the Trust, net of accrued expenses and other liabilities, on the date the order to purchase is properly received, as the number of Shares to be created under the purchase order is in proportion to the total number of Shares outstanding on the date the order is received. Each night, the Sponsor will publish the amount of bitcoin that will be required in exchange for each creation order. The Administrator determines the required deposit for a given day by dividing the number of bitcoin held by the Trust as of the opening of business on that business day, adjusted for the amount of bitcoin constituting estimated accrued but unpaid fees and expenses of the Trust as of the opening of business on that business day, by the quotient of the number of Shares outstanding at the opening of business divided by the aggregation of shares associated with a creation unit. The procedures by which an authorized participant can redeem one or more Creation Baskets mirror the procedures for the creation of Creation Baskets.

Rule 14.11(e)(4)—Commodity-Based Trust Shares

The Shares will be subject to BZX Rule 14.11(e)(4), which sets forth the initial and continued listing criteria applicable to Commodity-Based Trust Shares. The Exchange will obtain a representation that the Trust's NAV will be calculated daily and that these values and information about the assets of the Trust will be made available to all market participants at the same time. The Exchange notes that, as defined in Rule 14.11(e)(4)(C)(i), the Shares will be: (a) Issued by a trust that holds a specified commodity [73] deposited with the trust; (b) issued by such trust in a specified aggregate minimum number in return for a deposit of a quantity of the underlying commodity; and (c) when aggregated in the same specified minimum number, may be redeemed at a holder's request by such trust which will deliver to the redeeming holder the quantity of the underlying commodity.

Upon termination of the Trust, the Shares will be removed from listing. The Trustee, Delaware Trust Company, is a trust company having substantial capital and surplus and the experience and facilities for handling corporate trust business, as required under Rule 14.11(e)(4)(E)(iv)(a) and that no change will be made to the trustee without prior notice to and approval of the Exchange. The Exchange also notes that, pursuant to Rule 14.11(e)(4)(F), neither the Exchange nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions or delays in calculating or disseminating any underlying commodity value, the current value of the underlying commodity required to be deposited to the Trust in connection with issuance of Commodity-Based Trust Shares; resulting from any negligent act or omission by the Exchange, or any agent of the Exchange, or any act, condition or cause beyond the reasonable control of the Exchange, its agent, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission or delay in the reports of transactions in an underlying commodity. Finally, as required in Rule 14.11(e)(4)(G), the Exchange notes that any registered market maker (''Market Maker'') in the Shares must file with the Exchange in a manner prescribed by the Exchange and keep current a list identifying all accounts for trading in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, which the registered Market Maker may have or over which it may exercise investment discretion. No registered Market Maker shall trade in an underlying commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, in an account in which a registered Market Maker, directly or indirectly, controls trading activities, or has a direct interest in the profits or losses thereof, which has not been reported to the Exchange as required by this Rule. In addition to the existing obligations under Exchange rules regarding the production of books and records (see, *e.g.,* Rule 4.2), the registered Market Maker in Commodity-Based Trust Shares shall make available to the Exchange such books, records or other information pertaining to transactions by such entity or registered or non-registered employee affiliated with such entity for its or their own accounts for trading the underlying physical commodity, related commodity futures or options on commodity futures, or any other related commodity derivatives, as may be requested by the Exchange.

[73] For purposes of Rule 14.11(e)(4), the term commodity takes on the definition of the term as provided in the Commodity Exchange Act. As noted above, the CFTC has opined that Bitcoin is a commodity as defined in Section 1a(9) of the Commodity Exchange Act. *See* Coinflip.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares. The Exchange will halt trading in the Shares under the conditions specified in BZX Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the bitcoin underlying the Shares; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(e)(4)(E)(ii), which sets forth circumstances under which trading in the Shares may be halted.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. BZX will allow trading in the Shares during all trading sessions on the Exchange. The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions. As provided in BZX Rule 11.11(a) the minimum price variation for quoting and entry of orders in securities traded on the Exchange is $0.01 where the price is greater than $1.00 per share or $0.0001 where the price is less than $1.00 per share.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and Bitcoin Futures via ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[74]

Information Circular

Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (i) The procedures for the creation and redemption of Baskets (and that the Shares are not individually redeemable); (ii) BZX Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (iii) how information regarding the IIV and the Trust's NAV are disseminated; (iv) the risks involved in trading the Shares outside of Regular Trading Hours[75] when an updated IIV will not be calculated or publicly disseminated; (v) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (vi) trading information.

In addition, the Information Circular will advise members, prior to the commencement of trading, of the prospectus delivery requirements applicable to the Shares. Members purchasing the Shares for resale to investors will deliver a prospectus to such investors. The Information Circular will also discuss any exemptive, no-action and interpretive relief granted by the Commission from any rules under the Act.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[76] in general and Section 6(b)(5) of the Act[77] in particular in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has approved numerous series of Trust Issued Receipts,[78] including Commodity-Based Trust Shares,[79] to be listed on U.S. national securities exchanges. In order for any proposed rule change from an exchange to be approved, the Commission must determine that, among other things, the proposal is consistent with the requirements of Section 6(b)(5) of the Act, specifically including: (i) The requirement that a national securities exchange's rules are designed to prevent fraudulent and manipulative acts and practices;[80] and (ii) the requirement that an exchange proposal be designed, in general, to protect investors and the public interest.

The Exchange believes that the proposal is, in particular, designed to protect investors and the public interest. With the growth of OTC Bitcoin Funds over the past year, so too has grown the potential risk to U.S. investors. Significant and prolonged premiums and discounts, significant premium/discount volatility, high fees, insufficient disclosures, and technical hurdles are putting U.S. investor money

[74] For a list of the current members and affiliate members of ISG, *see www.isgportal.com*.

[75] Regular Trading Hours is the time between 9:30 a.m. and 4:00 p.m. Eastern Time.

[76] 15 U.S.C. 78f.

[77] 15 U.S.C. 78f(b)(5).

[78] *See* Exchange Rule 14.11(f).

[79] Commodity-Based Trust Shares, as described in Exchange Rule 14.11(e)(4), are a type of Trust Issued Receipt.

[80] As the Exchange has stated in a number of other public documents, it continues to believe that bitcoin is resistant to price manipulation and that ''other means to prevent fraudulent and manipulative acts and practices'' exist to justify dispensing with the requisite surveillance sharing agreement. The geographically diverse and continuous nature of bitcoin trading render it difficult and prohibitively costly to manipulate the price of bitcoin. The fragmentation across bitcoin platforms, the relatively slow speed of transactions, and the capital necessary to maintain a significant presence on each trading platform make manipulation of bitcoin prices through continuous trading activity challenging. To the extent that there are bitcoin exchanges engaged in or allowing wash trading or other activity intended to manipulate the price of bitcoin on other markets, such pricing does not normally impact prices on other exchanges because participants will generally ignore markets with quotes that they deem non-executable. Moreover, the linkage between the bitcoin markets and the presence of arbitrageurs in those markets means that the manipulation of the price of bitcoin price on any single venue would require manipulation of the global bitcoin price in order to be effective. Arbitrageurs must have funds distributed across multiple trading platforms in order to take advantage of temporary price dislocations, thereby making it unlikely that there will be strong concentration of funds on any particular bitcoin exchange or OTC platform. As a result, the potential for manipulation on a trading platform would require overcoming the liquidity supply of such arbitrageurs who are effectively eliminating any cross-market pricing differences. Furthermore, as noted herein, Sponsor has indicated its belief that the Reference Rate is reflective of a reasonable valuation of the average spot price of bitcoin and that resistance to manipulation is a priority aim of its design methodology.

at risk on a daily basis that could potentially be eliminated through access to a bitcoin ETP. As such, the Exchange believes that this proposal acts to limit the risk to U.S. investors that are increasingly seeking exposure to bitcoin through the elimination of significant and prolonged premiums and discounts, significant premium/discount volatility, the reduction of management fees through meaningful competition, the avoidance of risks associated with investing in operating companies that are imperfect proxies for bitcoin exposure, and protection from risk associated with custodying spot bitcoin by providing direct, 1-for-1 exposure to bitcoin in a regulated, transparent, exchange-traded vehicle designed to reduce the likelihood of significant and prolonged premiums and discounts with its open-ended nature as well as the ability of market participants (*i.e.,* market makers and authorized participants) to create and redeem on a daily basis.

The Exchange also believes that this proposal is consistent with the requirements of Section 6(b)(5) of the Act and that it has sufficiently demonstrated that, on the whole, the manipulation concerns previously articulated by the Commission are sufficiently mitigated to the point that they are outweighed by quantifiable investor protection issues that would be resolved by approving this proposal. Specifically, the Exchange believes that the significant increase in trading volume in Bitcoin Futures, the growth of liquidity at the inside in the spot market for bitcoin, and certain features of the Shares and the Reference Rate mitigate potential manipulation concerns to the point that the investor protection issues that have arisen from the rapid growth of over-the-counter bitcoin funds since the Commission last reviewed an exchange proposal to list and trade a bitcoin ETP, including premium/discount volatility and management fees, should be the central consideration as the Commission determines whether to approve this proposal.

(i) Designed To Prevent Fraudulent and Manipulative Acts and Practices

In order to meet this standard in a proposal to list and trade a series of Commodity-Based Trust Shares, the Commission requires that an exchange demonstrate that there is a comprehensive surveillance-sharing agreement in place [81] with a regulated market of significant size. Both the Exchange and CME are members of ISG.[82] The only remaining issue to be addressed is whether the Bitcoin Futures market constitutes a market of significant size, which the Exchange believes that it does. The terms ''significant market'' and ''market of significant size'' include a market (or group of markets) as to which: (a) There is a reasonable likelihood that a person attempting to manipulate the ETP would also have to trade on that market to manipulate the ETP, so that a surveillance-sharing agreement would assist the listing exchange in detecting and deterring misconduct; and (b) it is unlikely that trading in the ETP would be the predominant influence on prices in that market.[83]

The Commission has also recognized that the ''regulated market of significant size'' standard is not the only means for satisfying Section 6(b)(5) of the act, specifically providing that a listing exchange could demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement.[84]

(a) Manipulation of the ETP

The significant growth in Bitcoin Futures across each of trading volumes, open interest, large open interest holders, and total market participants since the Wilshire Phoenix Disapproval was issued are reflective of that market's growing influence on the spot price, which according to the academic research cited above, was already leading the spot price in 2018 and 2019. Where Bitcoin Futures lead the price in the spot market such that a potential manipulator of the bitcoin spot market (beyond just the constituents of the Reference Rate [85]) would have to participate in the Bitcoin Futures market, it follows that a potential manipulator of the Shares would similarly have to transact in the Bitcoin Futures market because the Reference Rate is based on spot prices. Further, the Trust only allows for in-kind creation and redemption, which, as further described below, reduces the potential for manipulation of the Shares through manipulation of the Reference Rate or any of its individual constituents, again emphasizing that a potential manipulator of the Shares would have to manipulate the entirety of the bitcoin spot market, which is led by the Bitcoin Futures market. As such, the Exchange believes that part (a) of the significant market test outlined above is satisfied and that common membership in ISG between the Exchange and CME would assist the listing exchange in detecting and deterring misconduct in the Shares.

(b) Predominant Influence on Prices in Spot and Bitcoin Futures

The Exchange also believes that trading in the Shares would not be the predominant force on prices in the Bitcoin Futures market (or spot market) for a number of reasons, including the significant volume in the Bitcoin Futures market, the size of bitcoin's market cap (approximately $1 trillion), and the significant liquidity available in the spot market. In addition to the Bitcoin Futures market data points cited above, the spot market for bitcoin is also very liquid. According to data from CoinRoutes from February 2021, the cost to buy or sell $5 million worth of bitcoin averages roughly 10 basis points with a market impact of 30 basis points.[86] For a $10 million market order, the cost to buy or sell is roughly 20 basis points with a market impact of 50 basis points. Stated another way, a market participant could enter a market buy or sell order for $10 million of bitcoin and only move the market 0.5%. More strategic purchases or sales (such as

[81] As previously articulated by the Commission, ''The standard requires such surveillance-sharing agreements since ''they provide a necessary deterrent to manipulation because they facilitate the availability of information needed to fully investigate a manipulation if it were to occur.'' The Commission has emphasized that it is essential for an exchange listing a derivative securities product to enter into a surveillance-sharing agreement with markets trading underlying securities for the listing exchange to have the ability to obtain information necessary to detect, investigate, and deter fraud and market manipulation, as well as violations of exchange rules and applicable federal securities laws and rules. The hallmarks of a surveillance-sharing agreement are that the agreement provides for the sharing of information about market trading activity, clearing activity, and customer identity; that the parties to the agreement have reasonable ability to obtain access to and produce requested information; and that no existing rules, laws, or practices would impede one party to the agreement from obtaining this information from, or producing it to, the other party.'' The Commission has historically held that joint membership in ISG constitutes such a surveillance sharing agreement. *See* Wilshire Phoenix Disapproval.

[82] For a list of the current members and affiliate members of ISG, *see www.isgportal.com.*

[83] *See* Wilshire Phoenix Disapproval.

[84] *See* Winklevoss Order at 37580. The Commission has also specifically noted that it ''is not applying a ''cannot be manipulated'' standard; instead, the Commission is examining whether the proposal meets the requirements of the Exchange Act and, pursuant to its Rules of Practice, places the burden on the listing exchange to demonstrate the validity of its contentions and to establish that the requirements of the Exchange Act have been met. *Id.* at 37582.

[85] As noted above, the Constituent Bitcoin Exchanges are Bitstamp, Coinbase, Gemini, itBit and Kraken.

[86] These statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021.

using limit orders and executing through OTC bitcoin trade desks) would likely have less obvious impact on the market—which is consistent with MicroStrategy, Tesla, and Square being able to collectively purchase billions of dollars in bitcoin. As such, the combination of Bitcoin Futures leading price discovery, the overall size of the bitcoin market, and the ability for market participants, including authorized participants creating and redeeming in-kind with the Trust, to buy or sell large amounts of bitcoin without significant market impact will help prevent the Shares from becoming the predominant force on pricing in either the bitcoin spot or Bitcoin Futures markets, satisfying part (b) of the test outlined above.

(c) Other Means To Prevent Fraudulent and Manipulative Acts and Practices

As noted above, the Commission also permits a listing exchange to demonstrate that ''other means to prevent fraudulent and manipulative acts and practices'' are sufficient to justify dispensing with the requisite surveillance-sharing agreement. The Exchange believes that such conditions are present. Specifically, the significant liquidity in the spot market and the impact of market orders on the overall price of bitcoin mean that attempting to move the price of bitcoin is costly and has grown more expensive over the past year. In January 2020, for example, the cost to buy or sell $5 million worth of bitcoin averaged roughly 30 basis points (compared to 10 basis points in 2/2021) with a market impact of 50 basis points (compared to 30 basis points in 2/2021).[87] For a $10 million market order, the cost to buy or sell was roughly 50 basis points (compared to 20 basis points in 2/2021) with a market impact of 80 basis points (compared to 50 basis points in 2/2021). As the liquidity in the bitcoin spot market increases, it follows that the impact of $5 million and $10 million orders will continue to decrease the overall impact in spot price.

Additionally, offering only in-kind creation and redemption will provide unique protections against potential attempts to manipulate the Shares. While the Sponsor believes that the independently maintained and administered Reference Rate which it uses to value the Trust's bitcoin is itself resistant to manipulation based on the methodology further described below, the fact that creations and redemptions are only available in-kind makes the manipulability of the Reference Rate significantly less important. Specifically, because the Trust will not accept cash to buy bitcoin in order to create new shares or, barring a forced redemption of the Trust or under other extraordinary circumstances, be forced to sell bitcoin to pay cash for redeemed shares, the price that the Sponsor uses to value the Trust's bitcoin is not particularly important.[88] When authorized participants are creating with the Trust, they need to deliver a certain number of bitcoin per share (regardless of the valuation used) and when they're redeeming, they can similarly expect to receive a certain number of bitcoin per share. As such, even if the price used to value the Trust's bitcoin is manipulated (which the Sponsor believes that its methodology is resistant to), the ratio of bitcoin per Share does not change and the Trust will either accept (for creations) or distribute (for redemptions) the same number of bitcoin regardless of the value. This not only mitigates the risk associated with potential manipulation, but also discourages and disincentivizes manipulation of the Reference Rate because there is little financial incentive to do so.

Commodity-Based Trust Shares

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed on the Exchange pursuant to the initial and continued listing criteria in Exchange Rule 14.11(e)(4). The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Commodity-Based Trust Shares. The issuer has represented to the Exchange that it will advise the Exchange of any failure by the Trust or the Shares to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Trust or the Shares are not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 14.12. The Exchange may obtain information regarding trading in the Shares and listed bitcoin derivatives via the ISG, from other exchanges who are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.

Availability of Information

The Exchange also believes that the proposal promotes market transparency in that a large amount of information is currently available about bitcoin and will be available regarding the Trust and the Shares. In addition to the price transparency of the Reference Rate, the Trust will provide information regarding the Trust's bitcoin holdings as well as additional data regarding the Trust. The Trust will provide an IIV per Share updated every 15 seconds, as calculated by the Exchange or a third-party financial data provider during the Exchange's Regular Trading Hours (9:30 a.m. to 4:00 p.m. E.T.). The IIV will be calculated by using the prior day's closing NAV per Share as a base and updating that value during Regular Trading Hours to reflect changes in the value of the Trust's bitcoin holdings during the trading day.

The IIV disseminated during Regular Trading Hours should not be viewed as an actual real-time update of the NAV, which will be calculated only once at the end of each trading day. The IIV will be widely disseminated on a per Share basis every 15 seconds during the Exchange's Regular Trading Hours by one or more major market data vendors. In addition, the IIV will be available through on-line information services.

The website for the Trust, which will be publicly accessible at no charge, will contain the following information: (a) The current NAV per Share daily and the prior business day's NAV and the reported closing price; (b) the BZX Official Closing Price in relation to the NAV as of the time the NAV is calculated and a calculation of the premium or discount of such price against such NAV; (c) data in chart form displaying the frequency distribution of discounts and premiums of the Official Closing Price against the NAV, within appropriate ranges for each of the four previous calendar quarters (or for the life of the Trust, if shorter); (d) the prospectus; and (e) other applicable quantitative information. The Trust will also disseminate the Trust's holdings on a daily basis on the Trust's website. The price of bitcoin will be made available

[87] These statistics are based on samples of bitcoin liquidity in USD (excluding stablecoins or Euro liquidity) based on executable quotes on Coinbase Pro, Gemini, Bitstamp, Kraken, LMAX Exchange, BinanceUS, and OKCoin during February 2021.

[88] While the Reference Rate will not be particularly important for the creation and redemption process, it will be used for calculating fees.

by one or more major market data vendors, updated at least every 15 seconds during Regular Trading Hours. Information about the Reference Rate, including key elements of how the Reference Rate is calculated, will be publicly available at *https://www.cfbenchmarks.com.*

The NAV for the Trust will be calculated by the administrator once a day and will be disseminated daily to all market participants at the same time. Quotation and last-sale information regarding the Shares will be disseminated through the facilities of the CTA.

Quotation and last sale information for bitcoin is widely disseminated through a variety of major market data vendors, including Bloomberg and Reuters, as well as the Reference Rate. Information relating to trading, including price and volume information, in bitcoin is available from major market data vendors and from the exchanges on which bitcoin are traded. Depth of book information is also available from bitcoin exchanges. The normal trading hours for bitcoin exchanges are 24 hours per day, 365 days per year.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the listing and trading of an additional exchange-traded product that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2021–024 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2021–024. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2021–024 and should be submitted on or before May 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[89]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–07675 Filed 4–14–21; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91526; File No. SR–NASDAQ–2021–018]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the Implementation Date of Enhancements to the End of Day Summary Message on Nasdaq Last Sale Plus to May 17, 2021

April 9, 2021.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 6, 2021, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to extend the implementation date of its enhancements to the End of Day (''EOD'') summary message on Nasdaq Last Sale (''NLS'') Plus to May 17, 2021.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the

[89] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq is filing this proposal to extend the implementation date of its enhancements to the EOD summary message on NLS Plus to May 17, 2021.

Nasdaq proposed to enhance the EOD summary message on NLS Plus by replacing the current high, low and closing price of a security based on its trading on the Nasdaq, Nasdaq BX and Nasdaq PSX exchanges with the consolidated high, low and closing price as published by the SIPs, and adding the opening price of a security published by the SIPs to that message. These changes were filed by Nasdaq on February 17, 2021, and published in the **Federal Register** on March 8, 2021.[3]

Nasdaq initially proposed that this change become operative on April 12, 2021. Due to a customer request to allow more weekend testing in advance of the date of launch, Nasdaq has decided to delay the implementation of this new functionality to May 17, 2021. Nasdaq announced the new implementation date on a Data Technical News Announcement disseminated on March 11, 2021.[4]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Section 6(b)(5) of the Act,[6] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

The purpose of this proposal is to inform the SEC and market participants of the new implementation date for the enhancements to the EOD summary message on NLS Plus. This functionality was previously proposed in a rule filing that was submitted to the SEC, and this proposal does not change the substance of that filing. Nasdaq is delaying the implementation date to allow for additional weekend testing prior to implementation.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. As explained above, the purpose of this proposal is to inform the SEC and market participants of the new implementation date for the enhancements to the EOD summary message on NLS Plus, and the Exchange does not expect the date change to place any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[7] and Rule 19b–4(f)(6) thereunder.[8]

A proposed rule change filed under Rule 19b–4(f)(6)[9] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[10] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay. Waiver of the operative delay would allow the Exchange to immediately extend the implementation date for the changes to the NLS Plus EOD summary message from April 12, 2021 to May 17, 2021 and allow market participants to engage in additional weekend testing prior to implementation. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.[11]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NASDAQ–2021–018 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NASDAQ–2021–018. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

[3] *See* Securities Exchange Act Release No. 91241 (March 2, 2021), 86 FR 13427 (March 8, 2021) (SR–Nasdaq–2021–010).

[4] Data Technical News #2021–7 (March 11, 2021), available at *http://www.nasdaqtrader.com/TraderNews.aspx?id=dtn2021-7*.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2021–018 and should be submitted on or before May 6, 2021.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–07678 Filed 4–14–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–91528; File No. SR–CBOE–2020–117]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Amend Certain Rules To Accommodate the Listing and Trading of Index Options With an Index Multiplier of One

April 9, 2021.

I. Introduction

On December 23, 2020, Cboe Exchange, Inc. (''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to allow the Exchange to list and trade certain index options with an index multiplier of one (''micro-options''). The proposed rule change was published for comment in the **Federal Register** on January 11, 2021.[3] On February 24, 2021, the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[4] On March 30, 2021, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change in its entirety.[5] The Commission is publishing this notice to solicit comments on the Exchange's proposal, as modified by Amendment No. 1, from interested persons and is approving the Exchange's proposal, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange proposes to amend its rules to allow the listing and trading of micro-options on broad-based indexes that have an index value of at least 100.[6] Currently, the Exchange may list options on broad-based indexes that satisfy the initial and maintenance criteria in Rule 4.10, and, according to the Exchange, it presently lists options on 12 broad-based indexes with an underlying index value of at least 100. These 12 broad-based indexes are listed below, along with their closing values as of March 30, 2021, as provided by the Exchange.[7]

Index (option symbol)	Current value
S&P 500 Index (SPX)	3,958.55
Mini-S&P 500 Index (XSP)	395.86
Russell 2000 Index (RUT)	2,195.80
Mini-Russell 200 Index (MRUT)	219.58
Dow Jones Industrial Average (DJX)	[8] 330.67
S&P 100 Index (OEX and XEO)	1,792.63
S&P 500 ESG Index (SPESG)	336.30
MSCI EAFE Index (MXEA)	2,216.07
MSCI Emerging Markets Index (MXEF)	1,319.50
Russell 1000 Growth Index (RLG)	2,412.94
Russell 1000 Value Index (RLV)	1,500.12
Russell 1000 Index (RUI)	2,228.28

[8] Options are based on 1/100th of the full value of the Dow Jones Industrial Average (''DJIA'').

Currently, the Exchange has designated an index multiplier of 100 for indexes it lists for trading. Pursuant to Rule 4.11, the Exchange may determine the index multiplier of an option, which is the amount specified in the contract by which the current index value is multiplied to arrive at the value required to be delivered upon valid exercise of the contract.[9] The Exchange generally specifies the index multiplier in the specifications for an index option.[10] Similarly, Article I, Section 1, I(3) of the Options Clearing Corporation (''OCC'') By-Laws defines ''index multiplier'' as the dollar amount (as specified by the Exchange on which such contract is traded) by which the current index value is to be multiplied to obtain the aggregate current index value. The Exchange states that, while the OCC's By-Laws define a unit of trading for equity options as 100 shares if not otherwise specified, the definition of index multiplier does not include a default unit.[11] The Exchange therefore believes the current index multiplier definition in the OCC By-Laws permits any index multiplier specified by the listing exchange.

Additionally, the Exchange believes micro-options are covered by the disclosures in the Options Disclosure Document (''ODD''). The Exchange states that the ODD reflects the possibility of differing values of index multipliers when describing features of

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C.78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 90853 (January 5, 2021), 86 FR 2006. Comments on the proposed rule change can be found on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-117/srcboe2020117.htm.*

[4] *See* Securities Exchange Act Release No. 91194, 86 FR 12244 (March 2, 2021). The Commission designated April 11, 2021, as the date by which it should approve, disapprove, or institute proceedings to determine whether to disapprove the proposed rule change.

[5] In Amendment No. 1, the Exchange: (i) Narrowed the scope of the proposed rule change to permit the listing and trading of micro-options only on broad-based index options that have index values of at least 100, rather than all indexes; (ii) narrowed the scope of the proposal to remove all aspects of the proposal that would have permitted the trading of flexible index options (''FLEX Index Options'') with an index multiplier of one (''FLEX micro-index options''); and (iii) provided additional rationale and support for the proposed rule change. Amendment No. 1 is available on the Commission's website at: *https://www.sec.gov/comments/sr-cboe-2020-117/srcboe2020117-8566514-230802.pdf.*

[6] The Exchange states that it intends to file a Form 19b–4(e) with the Commission for any index option it lists for trading with an index multiplier of one pursuant to Rule 19b–4(e) of the Act.

[7] The Exchange states that it intends to initially list micro-options on only a single index and may expand the listing of micro-options in the future in response to customer demand for such additional products.

[9] However, certain other Exchange Rules reflect an index multiplier of 100, and the Exchange proposes to update those rules to reflect the potential for an index multiplier of one.

[10] Option specifications are available at: *cboe.com/tradable_products/.*

[11] *See* OCC By-Laws Article I, Section 1, U(5).

index options.[12] Specifically, the ODD states the total exercise price for an index option is the exercise price multiplied by the multiplier, and the aggregate premium is the premium multiplied by the multiplier.[13] As a result, the Exchange believes that the risk disclosures regarding index options in the ODD currently cover any risks associated with option index options with multipliers of one (and other amounts).

The proposed rule change amends various rules regarding index options to permit the Exchange to designate an index multiplier of one for broad-based indexes that have an index value of at least 100 on which it may list options.[14] As proposed, micro-options would trade in the same manner as other index options.[15] The table below demonstrates the differences between a micro-option and a standard index option on the SPX Index:

Term	Standard (index multiplier of 100)	Micro (index multiplier of 1)
Strike Price	3930	3930
Bid or offer	32.05	32.05
Total Value of Deliverable	$393,000	$3,930
Total Value of Contract	$3,205	$32.05

To differentiate a micro-option on an index from a standard index option, the Exchange would list micro-options with a different trading symbol than the standard index option with the same underlying index to reduce any potential confusion.[16]

Trading Hours

As proposed, micro-options will be available for trading during the same hours as standard index options pursuant to Rule 5.1(b)(2), which will generally be 9:30 a.m. to 4:15 p.m. ET.[17] To the extent an index option is authorized for trading during Global Trading Hours,[18] the Exchange may also list micro-options during that trading session as well, the hours for which trading session are 3:00 a.m. to 9:15 a.m. ET.

Expiration, Settlement, and Exercise Style

As proposed, the Exchange may list a micro-option on an index with the same expirations, settlements, and exercise styles as the standard index option overlying the same index. Consistent with existing rules for index options, the Exchange will generally allow up to six standard monthly expirations for micro-options [19] as well as up to 10 expiration months for Long-Term Equity Option Series (''LEAPS'').[20] For certain specified index options (including MXEA, MXEF, and SPESG options) and any class that the Exchange (as the Reporting Authority) uses to calculate a volatility index (currently, only SPX options are used by the Exchange to calculate a volatility index), the Exchange may list up to 12 standard monthly expirations for micro-options on those indexes.[21] The Exchange may also list up to the same maximum number of expirations permitted in Rule 4.13(a)(2) for micro-options on broad-based index options with nonstandard expirations in accordance with the Nonstandard Expirations Pilot Program.[22] Micro-options will be cash-settled contracts with European-style exercise in accordance with the listing criteria for those options.[23] Micro-options, like standard index options, with third-Friday expiration will also be A.M.-settled or P.M.-settled, as applicable, in accordance with the applicable listing criteria.[24]

As proposed, the Exchange may list micro-options over the same indexes with P.M.-settlement in certain instances (in addition to A.M.-settlement in accordance with the generic listing terms). Specifically, pursuant to Rule 4.13(c), the Exchange may open for trading Quarterly Index Expirations (''QIXs'') on certain specified index options. QIXs are index option contracts that expire on the last business day of a calendar quarter, and the Exchange may list up to eight near-term quarterly expirations for trading.[25] Currently, the index multiplier for QIXs may be 100 or 500. The proposed rule change amends Rule 4.13(c) to permit the index multiplier to also be one to accommodate the listing of QIX micro-options on the specified indexes.

In addition, the Exchange's Nonstandard Expirations Pilot Program currently allows it to list Weekly and End of Month (''EOM'') Expirations on any broad-based index.[26] Like standard index options with Weekly and EOM Expirations, micro-options on broad-based indexes with Weekly and EOM Expirations will be P.M.-settled and otherwise treated the same as options on the same underlying index that expire on the third Friday of the month. The maximum number of expirations that may be listed for each of the Weeklys and EOMs in a micro-option is the same as the maximum number of expirations permitted in Rule 4.13(a)(2) for micro-options on the same broad-based index.[27] The Exchange may currently list Weekly and EOM Expirations on broad-based indexes as a pilot, which pilot period currently expires on May 3, 2021.[28] The Exchange currently submits regular reports and data to the Commission regarding the Nonstandard Expirations Pilot Program. To the extent the Exchange lists any micro-options with Weekly or EOM Expirations pursuant to this pilot program, the Exchange states that it will include the same information with respect to micro-options that it does for standard options

[12] The ODD is available at *https://www.theocc.com/about/publications/character-risks.jsp*. The ODD states that the exercise price of a stock option is multiplied by the number of shares underlying the option to determine the aggregate exercise price and aggregate premium of that option. *See* ODD at 18. Similarly, the ODD states that the total exercise price for an index option is the exercise price multiplied by the multiplier, and the aggregate premium is the premium multiplied by the multiplier. *See* ODD at 8, 9, and 125.

[13] *See* ODD at 8, 9, and 125.

[14] The proposed rule change, as amended by Amendment No. 1, will not permit the trading of FLEX micro-index options.

[15] The proposed rule change defines ''micro-options'' in Rule 4.11 as a broad-based index option for which the value of the underlying index is at least 100 with an index multiplier of one. The proposed rule change adds that references to ''index option'' in the Rules include ''micro-option'' unless the context otherwise requires.

[16] For example, a standard index option for index ABC with an index multiplier of 100 may have symbol ABC, while a micro-option for index ABC with a multiplier of one may have symbol ABC9.

[17] Certain indexes close trading at 4:00 p.m. ET. *See* Rule 5.1.

[18] *See id.*

[19] *See* Rule 4.13(a)(2).

[20] *See* Rule 4.13(b). Index LEAPS may expire 12 to 180 months from the date of issuance.

[21] *See* Rule 4.13(a).

[22] *See* Rule 4.13(e).

[23] *See* Rule 4.10(f) (broad-based initial listing criteria) and (h) (MXEA and MXEF); *see also* Rule 4.13(a)(3).

[24] *See id.*

[25] *See* Rule 4.13(c).

[26] *See* Rule 4.13(e).

[27] *See id.*

[28] *See* Securities Exchange Act Release No. 90262 (October 23, 2020), 85 FR 68616 (October 29, 2020).

in the reports it submits to the Commission in accordance with the pilot program.

Similarly, the Exchange also currently has a pilot program under Rule 4.13, Interpretation and Policy .13, that allows the Exchange to list options on specified indexes (SPX, XSP, and MRUT) that expire on the third Friday of the month that are P.M.-settled. Under the Exchange's proposal, the Exchange may list micro-options on those same indexes pursuant to this pilot program, which pilot period currently expires on May 3, 2021.[29] As it will for the Nonstandard Expirations Pilot Program, to the extent the Exchange lists micro-options on the specified indexes pursuant to this P.M.-settlement pilot program, the Exchange states that it will include the same information with respect to micro-options that it does for standard options in the reports it submits to the Commission in accordance with the pilot program.

Exercise Prices

The Exchange proposes to adopt Rule 4.13, Interpretation and Policy .01(l) to provide that the interval between strike prices of series of micro-options will be $0.50 or greater.[30] The Exchange states that there are two important distinctions between micro-options and standard options due to the difference in multipliers, one of which is how the total deliverable value is calculated (the other is the meaning of bids and offers, as further discussed below). Specifically, proposed Rule 4.13, Interpretation and Policy .01(l) states that strike prices for micro-options are set at the same level as index options with an index multiplier of 100. For example, a micro-option call series with a strike price of 3,250 has a total deliverable value of $3,250 (3,250 × $1), while a standard option call series with a strike price of 3,250 has a total deliverable value of $325,000 (3,250 × $100).[31]

Minimum Increments

The Exchange proposes to amend Rule 5.4 to provide that a micro-option will have the same minimum increment for bids and offers as the minimum increment for a standard index option on the same index.[32] Specifically, proposed Rule 5.3(c)(2) provides that notwithstanding Rule 5.3(a),[33] bids and offers for a micro-option must be expressed in terms of dollars per 1/100th part of the total value of the contract. For example, an offer of ''0.50'' represents an offer of $0.50 for a micro-option.[34]

Appointment Weights

The Exchange proposes to add micro-options each as a Tier AA class with a Market-Maker appointment weight of .001.[35] The Exchange states that this is the same appointment weight as a majority of the other Tier AA options classes. The Exchange determines appointment weights of Tier AA classes based on several factors, including, but not limited to, competitive forces and trading volume.

Contract Size Limits

The proposed rule change will update various other provisions in the following rules to reflect that one-hundred micro-contracts overlying an index will be economically equivalent to one contract for a standard index option overlying the same index:

- *Rules 1.1 (definition of ''complex order'') and 5.65(d) (definition of ''complex trade''):* The proposed rule change adds to the definitions in each of Rules 1.1 (definition of ''complex order'') and 5.65(d) (definition of ''complex trade'') that for the purposes of applying the ratios set forth in the definitions to complex orders comprised of legs for both micro-options and standard options, 100 micro-option contracts represent one standard option contract.[36]
- *Rules 5.37 and 5.38:* Rules 5.37 and 5.38 describe the Exchange's Automated Improvement Mechanism for simple (''AIM'') and complex orders (''C–AIM''), respectively. There is no minimum size for an order submitted into an AIM or C–AIM Auction.[37] However, in an AIM Auction for orders less than 50 standard option contracts (or 500 mini-option contracts), the stop price must be at least one minimum increment better than the then-current national best-bid or offer or the order's limit price (if the order is a limit order), whichever is better. For orders of 50 standard option contracts (or 500 mini-option contracts) or more, the stop price must be at or better than the then-current national best-bid or offer or the order's limit price (if the order is a limit order), whichever is better.[38] The proposed rule change will add to Rule 5.37(b) that 5,000 micro-option

[29] *See* Securities Exchange Act Release Nos. 90263 (October 23, 2020), 85 FR 68611 (October 29, 202), and 91067 (February 5, 2021), 86 FR 9108 (February 11, 2021).

[30] Pursuant to Rule 4.13, Interpretation and Policy .01, the interval between strike prices of standard index options is generally $5.00 except for lower-priced strikes, for which the smallest interval is $2.50, subject to certain exceptions (including reduced-value index options, which may have strike intervals of no less than $0.50 or $1). The Exchange states that this is consistent with lower permissible strike intervals for certain reduced-value index options, which have the same practical effect as index options with a smaller multiplier.

[31] The Exchange states that this corresponds to the calculation of exercise prices for other types of options with a reduced multiplier. For example, Rule 4.5, Interpretation and Policy .18(b) provides that strike prices for mini-options (which have multipliers of 10 rather than 100, as set forth in Rule 4.5, Interpretation and Policy .18(a)) are set at the same level as for standard options. For example, a call series strike price to deliver 10 shares of stock at $125 per share has a total deliverable value of $1,250 (10 × 125) if the strike is 125, while a call series strike price to deliver 100 shares of stock at $125 per share has a total deliverable value of $12,500 (100 × 125).

[32] *See* Rule 5.4(a). The Exchange states that this corresponds to the provision regarding the minimum increment for mini-options.

[33] Rule 5.3(a) states that except as otherwise provided in Rule 5.3, bids and offers must be expressed in terms of dollar and decimals per unit of the underlying security or index. The Exchange believes that the proposed rule change is consistent with this provision, as a bid of 7 will represent a bid of 7 for an option contract having an index multiplier (*i.e.,* unit of trading) of one. However, the Exchange proposes to add a specific provision regarding the meaning of bids and offers for micro-options to provide clarity in its rules, and to maintain consistency in its rules, which currently contain a separate provision for mini-options, which as discussed above, have a reduced multiplier compared to standard options as micro-options do.

[34] An offer of ''0.50'' represents an offer of $50 for a standard index option with an index multiplier of 100.

[35] *See* Rule 5.50(g). While the appointment weights of Tier AA classes are not subject to quarterly rebalancing under Rule 5.50(g)(1), the Exchange represents that it regularly reviews the appointment weights of Tier AA classes to ensure that they continue to be appropriate.

[36] The Exchange states that this corresponds to the provision in those definitions regarding mini-options, which states that for the purpose of applying these ratios to complex orders comprised of legs for both mini-options and standard options, ten mini-option contracts represent one standard option contract. The proposed rule change also conforms the definition of ''complex order'' in Rule 1.1 to the definition of ''complex trade'' in Rule 5.65 to say that it may be comprised of different series in the same ''underlying security'' rather than the same ''class.'' As discussed above, micro-options will be a different class than standard index options overlying the same index. This accommodates, for example, the fact that a complex order could be comprised of mini-options and standard options overlying the same stock (as contemplated by the current definition) despite being in different classes. The proposed rule change also expands the definitions of complex order in Rule 1.1 and complex trade in Rule 5.65 to provide that it may similarly be comprised of different series in the same ''underlying index.'' The Exchange states that full-value indexes and reduced-value indexes are separate indexes under the Exchange Rules, so to the extent a multi-legged order whose legs overly different indexes (such as one leg with a full-value index and one leg with a reduced-value index) would not qualify for the definition of ''complex trade.''

[37] The Exchange states that in SPX during Regular Trading Hours, there is a maximum size of 10 contracts for orders submitted into AIM and C–AIM Auctions (in C–AIM, the maximum size is based on the smallest leg of the complex order). *See* Rules 5.37(a)(3) and 5.38(a)(3). The Exchange is not proposing any changes to Rules 5.37(a)(3) and 5.38(a)(3).

[38] *See* Rule 5.37(b).

contracts is the corresponding size for these stop price restrictions. Additionally, Rule 5.37(c) and 5.38(c) provide that no concurrent AIM or C–AIM Auctions, respectively, are permitted for orders less than 50 standard option contracts (or 500 mini-option contracts) (for C–AIM Auctions, the size is determined by the smallest leg of the complex order), but are permitted for orders of 50 standard option contracts (or 500 mini-option contracts) or greater (for C–AIM Auctions, the size is determined by the smallest leg of the complex order). The proposed rule change will add that 5,000 micro-option contracts is the corresponding size for determining whether concurrent auctions are permissible.

• *Rules 5.39 and 5.40:* Rules 5.39 and 5.40 describe the Exchange's Solicitation Auction Mechanism for simple (''SAM'') and complex (''C–SAM''), orders, respectively. An order, or the smallest leg of a complex order, must be for at least the minimum size designated by the Exchange (which may not be less than 500 standard option contracts or 5,000 mini-option contracts). The proposed rule change will add that 50,000 micro-option contracts is the corresponding minimum size for orders submitted into SAM or C–SAM Auctions.

• *Rule 5.87:* Rule 5.87(f) describes when a Floor Broker is entitled to cross a certain percentage of an order, subject to the requirements in that paragraph. Under that Rule, the Exchange may determine on a class-by-class basis the eligible size for an order that may be transacted pursuant to this paragraph; however, the eligible order size may not be less than 50 standard option contracts (or 500 mini-option contracts). The proposed rule change will add that 5,000 micro-option contracts is the corresponding minimum size for orders that may be crossed in accordance with this provision. Additionally, Rule 5.87, Interpretation and Policy .07(a) provides that Rule 5.86(e) does not prohibit a Trading Permit Holder (''TPH'') from buying or selling a stock, security futures or futures position following receipt of an order, including an option order, but prior to announcing such order to the trading crowd, provided that the option order is in a class designated as eligible for ''tied hedge'' transactions and within the eligibility size parameters, which are determined by the Exchange and may not be smaller than 500 standard option contracts (or 5,000 mini-option contracts). The proposed rule change adds that 50,000 micro-option contracts is the corresponding minimum size for orders that may qualify as tied hedge transactions and not be deemed a violation of Rule 5.86(e).

Position and Exercise Limits [39]

Rule 8.31 governs position limits for broad-based index options, and currently provides that there are no position limits for broad-based index option contracts (including reduced-value option contracts) on DJX, OEX, XEO, RUT, and SPX classes (among others). The position limits on other broad-based index options that the Exchange currently lists for trading are below:

Broad-Based index	Standard limit (on the same side of the market)
Russell 1000, Russell 1000 Growth, Russell 1000 Value	50,000 contracts (no more than 30,000 near-term).
MSCI Emerging Markets Index, MSCI EAFE Index	50,000 contracts.
Other	25,000 contracts (no more than 15,000 near-term).

The proposed rule change adds Rule 8.31(f) to provide that positions in micro-options (with an index multiplier of one) will be aggregated with positions in standard options (including reduced-value option contracts) (with an index multiplier of 100) on the same broad-based index and, for purposes of determining compliance with the position limits under Rule 8.31, 100 micro-option contracts with an index multiplier of one equal one standard option contract with an index multiplier of 100. The Exchange states that this is consistent with Rule 8.31(d), which similarly provides that positions in reduced-value index options are aggregated with positions in full-value index options based on economic equivalent values of those options.

Rule 8.42(b) governs exercise limits for index options and provides that exercise limits for index option contracts will be equivalent to the position limits prescribed for option contracts with the nearest expiration date in Rule 8.31, 8.32, or 8.34. As is the case for certain broad-based index options as noted above, there are no exercise limits for certain broad-based index options (including reduced-value option contracts). The proposed rule change adds to Rule 8.42(b) that there will similarly be no exercise limits on micro-option contracts on those same broad-based indexes.

Capacity and Regulation

The Exchange represents that it believes the Exchange and Options Price Reporting Authority (''OPRA'') have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of the micro-options. The Exchange states that it also understands that the OCC will be able to accommodate the listing and trading of micro-options. The Exchange believes that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior which might arise from listing and trading micro-options. The Exchange further states that current Exchange Rules that apply to the trading of other index options traded on the Exchange will also apply to the trading of micro-options, such as Exchange Rules governing customer accounts, margin requirements and trading halt procedures. The Exchange also states that TPHs that enter micro-option orders on behalf of customers, including retail customers, will continue to be subject to all Exchange Rules regarding doing business with the public.

III. Discussion and Commission Findings

After careful review of the proposal and the comments received, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[40] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5)

[39] This discussion focuses on position and exercise limits with respect to indexes on which the Exchange currently lists standard options and may also list micro-options. To the extent the Exchange lists micro-options on other indexes in the future, the Exchange states that they would be subject to the same position and exercise limits set forth in the applicable Rules, and similarly aggregated with standard options on the same indexes, as proposed.

[40] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

of the Act,[41] which requires, among other things, that the rules of a national securities exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

In support of its proposal, the Exchange states that the listing and trading of micro-options could benefit investors, particularly retail investors, by expanding investor choice and flexibility by providing them with the ability to trade certain index options and hedge their portfolios with a smaller outlay of capital. Similarly, one commenter expressed support for the proposal,[42] asserting that the listing and trading of micro-options could benefit investors by providing a more precise hedging tool. The Exchange explains that micro-options may appeal to investors who currently may not participate in the trading of certain index options because index options are generally higher-priced securities due to the high levels of the indexes. The Exchange believes micro-options could provide these investors with a point of entry into the index options market, which will make options overlying larger-valued broad-based indexes[43] more readily available as investing and hedging tools. The Exchange believes this may facilitate overall investor participation in the markets for index options, which may increase the depth and liquidity to the benefit of all investors. The Exchange states that it does not believe the proposed rule change will result in fragmentation of liquidity. In particular, the Exchange states that it has observed no fragmentation of liquidity in the markets for economically equivalent products that are listed today. The Exchange further states that it expects micro-options to generate new order flow to the Exchange, rather than diverting current order flow from standard options to micro-options.

The Commission believes that the listing and trading of micro-options on broad-based indexes that have a value of at least 100 could benefit investors by providing them with additional investment alternatives.[44] The Commission believes that, as stated by the Exchange, the listing and trading of micro-options could make options overlying higher-valued broad-based indexes more readily available to investors, thereby providing investors with an additional trading and hedging mechanism.[45] The Commission believes this proposal, as amended to include only higher-value broad-based indexes, strikes a reasonable balance between the Exchange's desire to offer a wider array of investment opportunities and the need to avoid unnecessary proliferation of options series. However, the Commission expects the Exchange to monitor the trading of micro-options to evaluate whether any issues develop.

The Commission also believes that the proposal is consistent with the Act, in particular the protection of investors and the public interest, as it includes several aspects designed to reduce potential investor confusion. In particular, the Commission believes that the aspects of the proposal related to the quoting and trading of micro-options provide clarity about the application of certain of the Exchange's rules to micro-options. The Commission believes that the proposed treatment of strike prices, minimum size of index options contracts, bids and offers, and position and exercise limits for micro-options is consistent with the Act, as these proposed changes should make clear how micro-options would be quoted and traded and are consistent with the treatment of certain reduced-value index options.[46] The Commission also believes that the use of different trading symbols for micro-options should help investors and other market participants to distinguish those options from the related standard options, reducing potential investor confusion. Lastly, the Exchange has stated that it plans to provide investor education on the uses and risks of micro-options through its current and expanded education platforms.

Additionally, the Commission believes that the proposed appointment weight for micro-options is consistent with the Act, as the initial appointment weight is designed to incentivize more Market-Makers to obtain an appointment in each micro-option that the Exchange will list, which may result in more liquidity and competitive pricing.

The Commission believes it is appropriate and consistent with the Act for the Exchange to list the same expirations, settlements, and exercise styles for micro-options as it may for standard index options.[47] In addition, the Exchange states that it and OPRA have the necessary systems capacity to handle the additional traffic associated with the listing of new series that may result from the introduction of the micro-options. The Exchange also states that the OCC will be able to accommodate the listing and trading of micro-options.

As a national securities exchange, the Exchange is required, under Section 6(b)(1) of the Act,[48] to enforce compliance by its members and persons associated with its members with the provisions of the Act, Commission rules and regulations thereunder, and its own rules. The Exchange states that its existing surveillance and reporting safeguards are designed to deter and detect possible manipulative behavior that might arise from listing and trading micro-options. In addition, micro-options will be traded under the Exchange's existing regulatory regime for index options, which includes, among other things, the Exchange's existing rules regarding customer protection. In particular, the Exchange states that TPHs that enter micro-option orders on behalf of customers, including retail customers, will continue to be subject to all Exchange rules regarding doing business with the public,

[41] 15 U.S.C. 78f(b)(5).

[42] *See* Letter to Vanessa Countryman, Secretary, Commission, from Milliman Financial Risk Management LLC, dated April 5, 2021. A second commenter expressed support for listing and trading FLEX micro-index options for similar reasons; however, the Exchange removed aspects of the proposal that would permit the Exchange to list FLEX micro-index options in Amendment No. 1. *See* Letter to Vanessa Countryman, Secretary, Commission, from Biju Kulathakal, Chief Executive Officer, Halo Investing, Inc., dated March 31, 2021.

[43] The Exchange also believes it is reasonable to limit micro-options to broad-based indexes with values of at least 100, as indexes with smaller values would have smaller notional values.

[44] The Commission has previously approved the listing and trading of options based on a reduced value of broad-based indexes, including 1/100th the value of the FTSE 100 Index and FTSE 250 Index,[44] and 1/10th the value of the Nasdaq 100 Index. *See* Securities Exchange Act Release Nos. 57654 (April 11, 2008), 73 FR 21003 (April 17, 2008). *See also* Securities Exchange Act Release No. 51121 (February 1, 2005), 70 FR 6476 (February 7, 2005).

[45] In Amendment No. 1, the Exchange provided examples of the trading of a micro-option as compared to a standard option on a broad-based index and the potential benefits for investors. *See* Amendment No. 1 at 7–11.

[46] In addition, the Exchange has made changes to various provisions in its rules to reflect that one hundred micro-option contracts overlying an index will be economically equivalent to one contract for a standard index option. *See* Rule 1.1 (definition of ''complex order''), Rules 5.37–5.40 (governing various auction mechanisms), Rule 5.65(d) (definition of ''complex trade''), and Rule 5.87 (crossing orders).

[47] As described above, to the extent the Exchange lists micro-options pursuant to the Nonstandard Expirations Pilot Program or its pilot regarding certain P.M.-settled index options, the Exchange states that it will include the same information with respect to micro-options that it does for standard options in the reports and data it provides to the Commission.

[48] 15 U.S.C. 78f(b)(1).

including those within Chapter 9 of the Exchange Rulebook.[49] The Commission believes that it is consistent with the Act to apply Exchange rules governing, among other things, customer accounts, margin requirements, and trading halt procedures to the proposed micro-options that are otherwise applicable to other index options. The Commission believes that the Exchange's rules governing the trading of the index options on the Exchange help to ensure the maintenance of fair and orderly markets for micro-options, which is consistent with the protection of investors and the public interest.

Accordingly, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act[50] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, as modified by Amendment No. 1, is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CBOE–2020–117 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2020–117. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2020–117, and should be submitted on or before May 6, 2021.

V. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the 30th day after the date of publication of notice of the filing of Amendment No. 1 in the **Federal Register**. Amendment No. 1 narrowed the scope of the proposed rule change, as well as provided additional rationale and support for the proposed rule change. Specifically, the Exchange (i) narrowed the scope of the proposed rule change to permit the listing and trading of micro-options only on broad-based index options that have index values of at least 100, rather than all indexes; (ii) narrowed the scope of the proposal to remove all aspects of the proposal that would have permitted the trading of FLEX micro-index options; and (iii) provided additional rationale and support for the proposed rule change. In support of the proposed rule change, the Exchange: Provided additional examples of how retail investors may use micro-options; emphasized that TPHs, in entering micro-option orders on behalf of customers, will continue to be subject to all Exchange Rules regarding doing business with the public; and represented that it will expand education offerings to inform investors of the benefits and risks of trading micro-options. The changes to the proposal and additional information in Amendment No. 1 do not raise any novel regulatory issues and assist the Commission in evaluating the Exchange's proposal and in determining that it is consistent with the Act. Accordingly, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[51] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[52] that the proposed rule change (SR–CBOE–2020–117), as modified by Amendment No. 1, be, and hereby is, approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[53]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–07674 Filed 4–14–21; 8:45 am]

BILLING CODE 8011–01–P

[49] The Exchange states these rules require, among other things, that: (i) A TPH may not accept an option order, including a micro-option order, from a customer unless that customer's account has been approved for options transactions in accordance with Rule 9.1; (ii) TPHs that conduct customer business, including retail customer business, must ensure they provide for appropriate supervisory control over that business and maintain customer records in accordance with Rule 9.2; and (iii) TPHs will also need to provide customers that trade micro-options (and any other option) with a copy of the ODD and amendments to the ODD in accordance with Rule 9.9 so that customers are informed of any risks associated with trading options, including micro-options.

[50] 15 U.S.C. 78f(b)(5).

[51] 15 U.S.C. 78s(b)(2).

[52] *Id.*

[53] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #16920 and #16921; Washington Disaster Number WA–00092]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Washington

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Washington (FEMA–4593–DR), dated 04/08/2021.

Incident: Severe Winter Storm, Straight-line Winds, Flooding, Landslides, and Mudslides.

Incident Period: 12/29/2020 through 01/16/2021.

DATES: Issued on 04/08/2021.

Physical Loan Application Deadline Date: 06/07/2021.

Economic Injury (EIDL) Loan Application Deadline Date: 01/10/2022.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Assistance,

U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on 04/08/2021, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Clallam, Columbia, Grays Harbor, Island, Jefferson, Klickitat, Lewis, Mason, Okanogan, Pacific, Pend Oreille, Skagit, Skamania, Snohomish, Spokane, Wahkiakum

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	2.000
Non-Profit Organizations without Credit Available Elsewhere	2.000
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	2.000

The number assigned to this disaster for physical damage is 16920 B and for economic injury is 16921 0.

(Catalog of Federal Domestic Assistance Number 59008)

James Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2021–07729 Filed 4–14–21; 8:45 am]

BILLING CODE 8026–03–P

DEPARTMENT OF STATE

[Public Notice: 11393]

Designations of Russian Entities and Individuals

ACTION: Notice of Designation of Five Russian Entities and two Russian Individuals Pursuant to Executive Order 13382.

SUMMARY: Pursuant to the authority in the Executive Order ''Blocking Property of Weapons of Mass Destruction Proliferators and Their Supporters,'' the State Department, in consultation with the Secretary of the Treasury and the Attorney General, has determined that FEDERAL SECURITY SERVICE, STATE SCIENTIFIC RESEARCH INSTITUTE OF ORGANIC CHEMISTRY AND TECHNOLOGY, 33RD SCIENTIFIC RESEARCH AND TESTING INSTITUTE, the 27TH SCIENTIFIC CENTER, the MAIN INTELLIGENCE DIRECTORATE, ALEXANDER YEVGENIYEVICH MISHKIN, and ANATOLIY VLADIMIROVI CHEPIGA engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery (including missiles capable of delivering such weapons), including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by Russia.

DATES: The designation of these persons was effective on March 2, 2021.

FOR FURTHER INFORMATION CONTACT: Office of Counterproliferation Initiatives, Bureau of International Security and Nonproliferation, Department of State, Washington, DC 20520, tel.: 202–736–7065.

SUPPLEMENTARY INFORMATION: On June 28, 2005, the President, invoking the authority, *inter alia,* of the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) (''IEEPA''), issued Executive Order 13382 (70 CFR 38567, July 1, 2005) (the ''Order''), effective at 12:01 a.m. eastern daylight time on June 30, 2005. In the Order the President took additional steps with respect to the national emergency described and declared in Executive Order 12938 of November 14, 1994, regarding the proliferation of weapons of mass destruction and the means of delivering them.

Section 1 of the Order blocks, with certain exceptions, all property and interests in property that are in the United States, or that hereafter come within the United States or that are or hereafter come within the possession or control of United States persons, of: (1) The persons listed in the Annex to the Order; (2) any foreign person determined by the Secretary of State, in consultation with the Secretary of the Treasury, the Attorney General, and other relevant agencies, to have engaged, or attempted to engage, in activities or transactions that have materially contributed to, or pose a risk of materially contributing to, the proliferation of weapons of mass destruction or their means of delivery, including any efforts to manufacture, acquire, possess, develop, transport, transfer or use such items, by any person or foreign country of proliferation concern; (3) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State, the Attorney General, and other relevant agencies, to have provided, or attempted to provide, financial, material, technological or other support for, or goods or services in support of, any activity or transaction described in clause (2) above or any person whose property and interests in property are blocked pursuant to the Order; and (4) any person determined by the Secretary of the Treasury, in consultation with the Secretary of State, the Attorney General, and other relevant agencies, to be owned or controlled by, or acting or purporting to act for or on behalf of, directly or indirectly, any person whose property and interests in property are blocked pursuant to the Order.

As a result of this action, pursuant to the authority in section 1(a)(ii) of Executive Order 13382, all property and interests in property of aforementioned seven persons that are in the United States, or that hereafter come within the United States or that are or hereafter come within the possession or control of United States persons are blocked and may not be transferred, paid, exported, withdrawn, or otherwise dealt in.

Information on the designees:

ENTITY 1

ENTITY: FEDERAL SECURITY SERVICE
ENTITY AKA: FEDERALNAYA SLUZHBA BEZOPASNOSTI
ENTITY AKA: FSB
ENTITY ADDRESS: ULITSA KUZNETSKIY MOST, DOM 22, MOSCOW, RUSSIA, POSTAL CODE 107031
ENTITY ADDRESS: LUBYANSKAYA PLOSCHAD, DOM 2, MOSCOW, RUSSIA, POSTAL CODE 107031

ENTITY 2

ENTITY: STATE SCIENTIFIC RESEARCH INSTITUTE OF ORGANIC CHEMISTRY AND TECHNOLOGY
ENTITY AKA: GOSNIIOKHT
ENTITY ADDRESS: SHOSSE ENTUZIASTOV 23, MOSCOW, MOSCOW OBLAST, RUSSIA

ENTITY 3

ENTITY: 33RD SCIENTIFIC RESEARCH AND TESTING INSTITUTE
ENTITY AKA: 33RD TSNIII
ENTITY ADDRESS: 1 ULITSA KRASNOZNAMENNAYA, VOLSK–18/SHIKHANY, SARATOV OBLAST, RUSSIA

ENTITY 4

ENTITY: 27TH SCIENTIFIC CENTER
ENTITY AKA: 27TH NTS

ADDRESS: BRIGADIRSKIY PEREULOK 13, 105005, MOSCOW, RUSSIA
COUNTRY: RUSSIA

ENTITY 5

ENTITY: MAIN INTELLIGENCE DIRECTORATE
ENTITY AKA: GLAVNOE RAZVEDYVATEL'NOE UPRAVLENIE
ENTITY AKA: GRU
ENTITY AKA: MAIN INTELLIGENCE DEPARTMENT
ENTITY AKA: MAIN DIRECTORATE OF THE GENERAL STAFF
ENTITY ADDRESS: KHOROSHEVSKOYE SHOSSE 76, KHODINKA, MOSCOW, RUSSIA
ENTITY ADDRESS: MINISTRY OF DEFENCE OF THE RUSSIAN FEDERATION, FRUNZENSKAYA NAB., 22/2, MOSCOW, RUSSIA, POSTAL CODE 119160
COUNTRY: RUSSIA

INDIVIDUAL 1

INDIVIDUAL: ALEXANDER YEVGENIYEVICH MISHKIN
INDIVIDUAL AKA: ALEXANDER PETROV
INDIVIDUAL GENDER: MALE
INDIVIDUAL DATE OF BIRTH: JULY 13, 1979
PLACE OF BIRTH: LOYGA, RUSSIA; KOTLAS, RUSSIA
NATIONALITY: RUSSIA

INDIVIDUAL 2

INDIVIDUAL: ANATOLIY VLADIMIROVICH CHEPIGA
INDIVIDUAL AKA: RUSLAN BOSHIROV
GENDER: MALE
DATE OF BIRTH: APRIL 5, 1979; APRIL 12, 1978;
PLACE OF BIRTH: NIKOLAEVKA, AMUR OBLAST, RUSSIA; DUSHANBE, TAJIKISTAN
ADDRESS: MOSCOW, RUSSIA
NATIONALITY: RUSSIA

Gonzalo O. Suarez,

Acting Deputy Assistant Secretary, International Security and Nonproliferation, Department of State.

[FR Doc. 2021–07619 Filed 4–14–21; 8:45 am]

BILLING CODE 4710–27–P

DEPARTMENT OF STATE

[Public Notice: 11409]

Defense Trade Advisory Group; Notice of Open Meeting

The Defense Trade Advisory Group (DTAG) will meet in open session from 1:00 p.m. until 5:00 p.m. on Thursday, May 20, 2021. Based on federal and state guidance in response to the Covid–19 pandemic, the meeting will be held virtually. The virtual forum will open at 12:00 p.m. The membership of this advisory committee consists of private sector defense trade representatives, appointed by the Assistant Secretary of State for Political-Military Affairs, who advise the Department on policies, regulations, and technical issues affecting defense trade. The DTAG was established as an advisory committee under the authority of 22 U.S.C. Sections 2651a and 2656 and the Federal Advisory Committee Act, 5 U.S.C. App. The purpose of the meeting will be to discuss current defense trade issues and topics for further study. The following agenda topics will be discussed, and final reports presented: (1) Provide recommendations for revisions to the International Traffic in Arms Regulations (ITAR) § 123.17 with regard to exemptions for Personal Protective Gear. (2) Incorporate relevant legislative and treaty requirements into its analysis on an alternative reporting approach (related to Part 130 Reporting), paying particular attention to which reporting requirements mandate DDTC to report contributions, gifts, commissions, or fees offered; versus paid, or both. (3) Develop comprehensive ITAR citations of the various compliance requirements that could be used to assist companies and universities to develop robust ITAR compliance programs.

The meeting will be held virtually via WebEx. There will be one WebEx invitation for each attendee, and only the invited attendee should use the invitation. In addition, each attendee should access the virtual meeting from a private location. Please let us know if you need any of the following accommodations: Live captions, digital/text versions of webinar materials, or other (please specify).

Members of the public may attend this virtual session and may submit questions by email following the formal DTAG presentation. Members of the public may also submit a brief statement (less than three pages) to the committee in writing for inclusion in the public minutes of the meeting. Each member of the public that wishes to attend this session must provide: Name and contact information, including an email address and phone number, and any request for reasonable accommodation to the DTAG Designated Federal Officer (DFO), Deputy Assistant Secretary Michael Miller, via email at *DTAG@state.gov* by COB Tuesday, May 18, 2021.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Eisenbeiss, PM/DDTC, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political-Military Affairs, U.S. Department of State, Washington, DC 20522–0112; telephone (202) 663–2835 or email *DTAG@state.gov.*

Michael F. Miller,

Designated Federal Officer, Defense Trade Advisory Group, U.S. Department of State.

[FR Doc. 2021–07731 Filed 4–14–21; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF STATE

[Delegation of Authority No. 513]

Delegation of the Authorities of the Secretary

By virtue of the authority vested in the Secretary of State by the laws of the United States, including 22 U.S.C. 2651a, I hereby delegate to the Deputy Secretary and the Deputy Secretary for Management and Resources, to the extent authorized by law, all authorities and functions vested in the Secretary of State or the head of agency by any act, order, determination, delegation of authority, regulation, or executive order, now or hereafter issued.

This Delegation includes all authorities and functions that have been or may be delegated or re-delegated to other Department officials but does not repeal delegations to such officials.

The Secretary of State may exercise any authority or function delegated herein.

This Delegation of Authority supersedes Delegation of Authority 245–2, dated July 31, 2017.

This memorandum shall be published in the **Federal Register**.

Dated: April 7, 2021.

Antony J. Blinken,

Secretary of State, Department of State.

[FR Doc. 2021–07744 Filed 4–14–21; 8:45 am]

BILLING CODE 4710–10–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No.—2021–2064]

Petition for Exemption; Summary of Petition Received; Ohio State University

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of

this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before May 5, 2021.

ADDRESSES: Send comments identified by docket number FAA–2021–0147 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Jimeca Callaham, (202) 267–0312, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Timothy R. Adams

Deputy Executive Director, Office of Rulemaking.

PETITION FOR EXEMPTION

Docket No.: FAA–2021–0147.

Petitioner: Ohio State University.

Section(s) of 14 CFR Affected: §§ 61.160(b)(3)(i) and (ii).

Description of Relief Sought: The Ohio State University (OSU) is petitioning for an exemption from § 61.160(b)(3)(i) and (ii), to the extent necessary to allow two specific OSU students to substitute certain training received outside the university for part of OSU's approved part 141 curriculum in order to be eligible for an Airline Transport Pilot Certificate with Restricted Privileges (R–ATP). These two students sought training outside OSU during temporary closures in Ohio caused by the Coronavirus Disease 2019 (COVID–19).

[FR Doc. 2021–07673 Filed 4–14–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Release Certain Properties From All Terms, Conditions, Reservations and Restrictions of a Quitclaim Deed Agreement Between the City of Melbourne and the Federal Aviation Administration for the Melbourne International Airport, Melbourne, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comment.

SUMMARY: The FAA hereby provides notice of intent to release 4.93 acres at the Melbourne International Airport, Melbourne, FL from the conditions, reservations, and restrictions as contained in a Quitclaim Deed agreement between the FAA and the City of Melbourne, dated August 6, 1947. The release of property will allow the City of Melbourne to use the property for other than aeronautical purposes. The property is located located on the northwest corner of West NASA Blvd. and Air Terminal Parkway at the Melbourne International Airport in Brevard County. The parcel is currently designated as surplus property. The property will be released of its federal obligations for the purpose of providing a long-term non-aeronautical lease to a private developer to build a hotel, hotel parking area, and storm water detention pond. The fair market value lease of this parcel has been determined to be $197,570,74.

Documents reflecting the Sponsor's request are available, by appointment only, for inspection at the Melbourne International Airport and the FAA Airports District Office.

DATES: Comments are due on or before May 17, 2021.

ADDRESSES: Documents are available for review at Melbourne International Airport, and the FAA Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819. Written comments on the Sponsor's request must be delivered or mailed to: Marisol Elliott, Community Planner, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819.

FOR FURTHER INFORMATION CONTACT: Marisol Elliott, Community Planner, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819. Phone: (407) 487–7231.

SUPPLEMENTARY INFORMATION: Section 125 of The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR–21) requires the FAA to provide an opportunity for public notice and comment prior to the ''waiver'' or ''modification'' of a sponsor's Federal obligation to use certain airport land for non-aeronautical purposes.

Bartholomew Vernace,

Manager, Orlando Airports District Office, Southern Region.

[FR Doc. 2021–07664 Filed 4–14–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year 2021 Competitive Research Funding Opportunity: Transit Workforce Center (TWC)

AGENCY: Federal Transit Administration (FTA), U.S. Department of Transportation (DOT).

ACTION: Notice of Funding Opportunity (NOFO).

SUMMARY: This notice announces the availability of $5 million in Fiscal Year (FY) 2020 and 2021 Technical Assistance and Workforce Development funds to establish a Transit Workforce Center (TWC) that supports public transit agencies' workforce development needs for all modes of public transit across urban, tribal, and rural entities. The overarching mission of this new center is to assist public transit agencies to recruit, hire, train, and retain the diverse workforce needed now and in the future.

DATES: Complete proposals for the Transit Workforce Center must be submitted electronically through the *GRANTS.GOV* ''APPLY'' function by 11:59 p.m. Eastern time on May 10, 2021. Late applications will not be accepted. Prospective applicants should initiate the process by registering on the *GRANTS.GOV* website promptly to ensure completion of the application process before the submission deadline. Instructions for applying can be found on FTA's website at *http://transit.dot.gov/howtoapply* and in the ''FIND'' module of *GRANTS.GOV*. The funding opportunity ID is FTA–2021–002–TRI–WD. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: If you have questions or need additional information about this Notice of Funding Opportunity, you may contact Ms. Betty Jackson by phone at (202) 366–1730 or by email at *Betty.Jackson@dot.gov.*

A TDD is available for individuals who are deaf or hard of hearing at 800.877.8339. Prospective applicants may visit the following website for more information: *https://www.transit.dot.gov/research-innovation/workforce-development-initiative.*

SUPPLEMENTARY INFORMATION:

Table of Contents

A. Program Description

This Notice of Funding Opportunity (NOFO), under Federal Assistance Listing number 20.531, supports FTA's strategic goals and objectives through the timely and efficient investment in public transportation. The FTA solicits proposals for a cooperative agreement to establish, build and manage a Transit Workforce Center (TWC) that is a sustainable public transportation workforce development technical assistance center. The mission of the TWC is to help transit agencies recruit, hire, train, and retain the diverse workforce they need for today and tomorrow.

Even as public transit agencies face daunting workforce development challenges—that have been exacerbated by the coronavirus disease 2019 (COVID–19) public health emergency—there are tremendous opportunities for the transit workforce to play a central role in helping achieve President Biden's vision for America to Build Back Better.

Frontline workforce shortages continue, especially in positions relating to bus operation and bus maintenance. Addressing these shortages by developing a skilled transit workforce will create good-paying, secure jobs for workers in communities throughout the country.

A well-trained transit workforce is also central to the United States' response to COVID–19. In response to the public health emergency, transit agencies have had to train workers on various new protocols for drivers and operators to ensure safe operations. In addition, deeper and more frequent sanitation and decontamination of stations and rolling stock may require new procedures and additional workers. Effective workforce training will help keep workers and transit riders safe and will speed our recovery from this public health emergency.

In the longer term, technology has the potential to open new doors for a well-trained transit workforce. Advanced technologies such as smart systems and transit automation, increased rider expectations for real-time information, and new service models utilizing shared services, micro-transit, and data analytics have the potential to transform the transit industry. Training the transit workforce of the future is essential to ensuring that the United States remains competitive in the global economy.

The transit workforce will also play a central role in responding to the climate crisis. With the increased adoption of energy-efficient low- or no-emission vehicles, transit fleets are changing. Maintaining these vehicles requires new skill sets, including knowledge of electricity, charging systems, and a variety of fuels. These vehicles also often require enhancements to maintenance facilities, equipment, and protocols. In furtherance of President Biden's Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad,* these changes in vehicle technologies will offer ''opportunities to create well-paying union jobs to build a modern and sustainable infrastructure, deliver an equitable, clean energy future, and put the United States on a path to achieve net-zero emissions, economy-wide, by no later than 2050.'' It is within this evolving and complex landscape that FTA is launching this new resource for transit agencies.

The TWC will perform two primary programs: 1. Conduct technical assistance activities within and for transit agencies that promote more effective and efficient training of frontline workers involved in public transportation maintenance and operations, which is needed to support transformations in public transportation services and assets; and 2. Implement technical assistance activities through collaborative partnerships between transit agency management and labor, including apprenticeships, thereby providing an opportunity to begin addressing social inequities that exist in public transit and creating diversity within and among the transit industry workforce.

Over the last ten years, FTA invested more than $20 million for Innovative Transit Workforce Development Grants. Over forty-five different grants explored projects in several areas, including: (1) New Entrants; (2) Incumbent Worker Training; (3) Youth Engagement and Outreach; (4) Internships, Apprenticeships, Work-Based Skills Training or New Technology Training; and (5) Curriculum Development. FTA recently released an evaluation of the 2015 grants, and a summary of findings from all the projects (see Section H for links to these reports). For just the 2015 grants, over 7,500 individuals participated in the various workforce development projects. Many historically underserved individuals benefited from these employment projects, including veterans, women, racial and ethnic minorities, low-income individuals, re-entering citizens, individuals with disabilities, persons from immigrant communities, as well as urban, tribal, and rural transit providers. The TWC will act as a clearinghouse for previously completed Innovative Transit Workforce Development reports, project models, training materials and curricula, for ease of dissemination.

In December 2018, with facilitation from the Transportation Learning Center and the National Transit Institute at Rutgers University, FTA hosted a two-day gathering of more than two dozen transit industry labor and management representatives to engage in in-depth discussions on frontline workforce training needs across the country. This session was held to build on the results of FTA's more than 45 workforce projects. The meeting also helped to identify immediate, short-term, and long-term training needs for the frontline public transportation workforce in the U.S. and ways to develop apprenticeship and formal training programs to support these needs. The group focused on three key priority areas of the frontline workforce development life cycle—Recruitment, Development, and Retention—and developed recommended actions for each of these priority areas. The

synthesis report can be found on FTA's website and is linked in Section H.

The TWC will build upon the results and the findings of these investments and meetings and function as a one-stop shop for transit agencies, stakeholders and providers to find information and receive assistance on all transit workforce related areas. The TWC will help agencies identify the best use for the 0.5% of their FTA Urbanized Area Formula Program funds eligible for workforce programs. See 49 U.S.C. 5314(b)(4). The primary activities of the TWC are to:

1. Provide public transportation workforce development technical assistance to public transit agencies;
2. Provide targeted workforce development training to public transit agencies as funds allow, if not provided by the National Transit Institute;
3. Develop roadmaps for public transportation agency workforce functions and personnel that address readiness for implementing transformative technologies and practices;
4. Develop outreach and marketing materials on promising workforce development projects for dissemination to public transit agencies;
5. Lead workforce strategic planning activities for public transit agencies and FTA;
6. Create a sustainable funding model among its partnerships to continue after FTA's initial funding ends; and
7. Develop key performance metrics as well as identify dataset needs and data analytic activities to monitor trends in public transportation workforce needs and issues, including identification of areas to further diversity, equity and inclusion.

The TWC will be managed by the recipient of the cooperative agreement in coordination with FTA headquarters staff. It will be the first FTA-funded technical assistance resource to support public transit workforce development. Eligible applicants are national nonprofit organizations with a demonstrated capacity to develop and provide workforce development programs through labor management partnerships and apprenticeships.

This Notice solicits competitive proposals addressing the mission, goals, and tasks set forth for this new TWC, provides instructions for submitting proposals, and describes the evaluation criteria for proposal selection.

This announcement is available on the FTA website at: *https://www.fta.dot.gov/grants/130707.html.* A synopsis of this funding opportunity will be posted in the ''FIND'' module of the government-wide, electronic grants website called *GRANTS.GOV,* which can be accessed at this web address: *http://www.grants.gov.*

B. Federal Award Information

FTA will award the TWC as a cooperative agreement to a national nonprofit organization with a demonstrated capacity to develop and provide workforce development programs though labor management partnerships and apprenticeships. This cooperative agreement will be managed by the FTA Workforce Program manager in its headquarters office. FTA will fund up to 100 percent of the initial project, with a maximum of $5 million available for the first two years of the cooperative agreement with a start date to be determined in 2021, but FTA may give priority consideration to proposals that include local match. The local match can be derived through in-kind activities not funded by the Federal Government and match from other Federal Agencies as noted in the Coordinated Council on Access and Mobility resources on match. Applicants are particularly encouraged to find ways to leverage both FTA and Department of Labor funds and programs. Additional funding may be provided by other strategic partners to address critical transit workforce issues. Subsequent funding from FTA will depend upon decisions and program priorities established by the Secretary of Transportation, future authorizations and appropriations, and the TWC's annual performance reviews.

The maximum period of performance covered by the award amount shall not exceed twenty-four (24) months from the date of execution in FTA's electronic grants management system.

The FTA Administrator will determine the amount of funds to be awarded in the cooperative agreement, up to $5 million. This funding opportunity will be awarded under the terms of a cooperative agreement.

C. Eligibility Information

1. Eligible Applicants

Eligible lead applicants are national nonprofit organizations capable of a national reach with a demonstrated capacity to develop and provide workforce development programs though labor management partnerships, apprenticeships, among other applicable methods. The lead applicant may partner with other organizations as described below.

The cooperative agreement will be between FTA and the selected organization, which must have a primary or substantial interest in performing a majority of the work in the project and must not simply act as a pass-through for funds. Applicants may apply individually or in a group of eligible applicants. The group of eligible applicants must include a lead applicant as the primary recipient of Federal funds. Individuals, for-profit entities, and other Federal agencies are ineligible to apply for this funding.

2. Cost Sharing

The FTA will fund up to 100 percent Federal share, but may give priority consideration to proposals that include local match.

D. Application and Submission Information

1. Address To Request Application Package

Applications must be submitted electronically through *Grants.gov*. Mail and fax submissions will not be accepted. A complete proposal submission will consist of at least two files: (1) The Standard Form (SF) 424 Application for Federal Assistance, and (2) a narrative application document in Microsoft Word, Adobe Acrobat, or compatible file format. The SF–424 can be downloaded from *Grants.gov*. The required form and content of the narrative application are described below.

2. Content and Form of Application Submission

Proposals shall be submitted in a Microsoft Word, Adobe Acrobat, or compatible file format, double-spaced using Times New Roman, 12-point font. The proposal must contain the following components and adhere to the specified maximum lengths:

a. Cover sheet (1 page). The cover sheet must include the name of the entity submitting the proposal, the principal's name, title, and contact information (*e.g.,* address, phone, and email), and the name and contact information for the key point of contact for each function of the agreement referenced under the ''Program Description'' section of this Notice.

b. Abstract (not to exceed 4 pages). The abstract must include the following sections: Background, purpose, methodology, intended outcomes, and plan for evaluation.

c. Detailed budget proposal and budget narrative (not to exceed 3 pages).

d. Project narrative (not to exceed 25 pages). The applicant should submit a project narrative statement describing:

i. The methodology for addressing the project goals, objectives, activities, deliverables, milestones, timeline and

intended outcomes for achieving the goals outlined in the scope for the first year;

ii. The methodology for measuring the outputs, and benefits of the proposed project for which Federal assistance is being requested;

iii. The methodology used to develop performance measures and a data plan showing how the TWC team will assess success;

iv. How the applicant demonstrates an understanding of public transportation workforce needs, both broadly at a strategic level, and more specifically, at functional levels both for what types of skills/roles transit agencies need to succeed today and in the future;

v. The applicants' awareness not only of frontline worker needs, but also of new transit worker needs, associated with emerging technologies and service models;

vi. The applicants' dedication to and focus on furthering diversity and equity for transit workers;

vii. The applicants' dedication to and focus on emerging technology areas, including those relevant to responding to the climate crisis;

viii. The existing and future capacity of the organization to address the issues outlined in the proposal;

ix. A detailed plan for communication, technical assistance, and outreach at the State and local levels;

x. A detailed plan to address the three recommendations from the Government Accountability Office's (GAO) report dated May 6, 2019, titled ''*Transit Workforce Development: Improved Strategic Planning Practices Could Enhance FTA Efforts, GAO–19–290*'';

xi. A plan to work with stakeholders and build partnerships at the national level; and

xii. Staff qualifications including: (1) Prior experience providing technical assistance, especially related to public transit agencies' workforce development needs for all modes of public transit across urban, tribal, and rural entities, (2) prior experience implementing the other tasks outlined in this solicitation, (3) staff members' knowledge of issues related to the recruiting, hiring, training and retaining the diverse workforce needed now and in the future, and (4) a one-page biographical sketch for each staff member.

e. Additional Project Narrative Context. The application also should discuss how the recipient will perform the following short- and long-term activities:

Short-Term Activities:

(1) Hiring needed staff and setting up the new center, including developing an interactive website that houses and delivers a library of workforce development tools, topics, articles, best practices; acts as a clearinghouse for transit workforce information; and facilitates outreach.

(2) Developing an online fully functional workflow system TWC Help Desk that will enable email and phone technical assistance inquiries and responses on workforce development questions/topics; this system should be able to gather performance measures that track web-analytics, technical assistance requests, time to resolution of requests, types of requests, and enable a quarterly report to FTA on what activities have been completed, how many people have received assistance; the cost of that assistance; and the satisfaction of those who sought assistance.

(3) Creating a draft transit workforce development strategic plan and submitting it to FTA within six weeks of award that notes key workforce functions needed today and those that will need to be developed for the future.

(4) Based upon the final workforce strategic plan, develop recruitment, training and retention standards and best practices for both urban and rural transit entities operating all transit modes.

(5) Make recommendations to FTA on the data needs to help track and assess public transit workforce needs.

Long-term/ongoing activities:

(1) Promoting promising practices resulting from more than 45 FTA-funded workforce projects over the last ten years, through videos, pamphlets, and webinars;

(2) Providing a mentor/training program for transit instructors as resident instructors;

(3) Tracking and sharing results from successful apprenticeship programs;

(4) Providing peer-to-peer meeting exchanges and collaboration opportunities, while expanding dialogue with transit workforce industry partners and fostering relationships with other non-traditional Federal partners, in an effort to address social inequities and lack of racial diversity within and among the transit industry workforce;

(5) Developing written and electronic training materials that explain how to leverage funds from partners and to use the half percent available from some FTA formula funds (currently totaling over $30 Million annually) for workforce development/human resource activities;

(6) Developing a feedback system that enables opportunities for improvement of the Center's customer service, programs and processes; and

(7) Conducting an evaluation of the Center and its activities.

f. Evaluation Plan. Plan for evaluation of TWC, technical assistance center activities and performance measures (not to exceed 5 pages).

g. Supplemental Materials. Supplemental materials, such as letters of support, can be included in appendices that are beyond the page limit above but are not to exceed 15 additional pages.

h. Geographic Location, Target Groups, and Emphasis Areas. Give a precise location or locations of the proposed partners, while identifying their area(s) of expertise, and impacts expected from their direct involvement in the Center. Information or other graphic aids may be attached as needed.

i. Strategic Partners. FTA expects bidders to develop a broad base of partnerships for the TWC. Though there should be one overall responsible party, the approach to the work should be through a consortium, where different, experienced, organizations work together to meet the diverse needs of public transit agencies.

To be eligible for funding under this NOFO, applicants must demonstrate that the proposed project is supported by the primary eligible applicant in partnership with labor and management organizations and other external partners as needed.

Partner entities to the lead applicant could include, but are not limited to:

(1) Operators of public transportation.

(2) Educational institutions, which include entities providing professional accreditation, apprenticeship programs, degree, and/or certification programs, such as universities, community colleges, or trade schools, either non-profit or for-profit.

(3) Public workforce investment systems, such as local Workforce Investment Boards and their one-stop systems.

(4) Labor organizations, such as labor unions and labor management organizations.

(5) Non-profit organizations that support the mission of transit and transportation workforce development.

An applicant should include a letter of confirmed support from each partner as part of its application. Applicants also must include sufficient evidence of the partnership. Sufficient evidence may include a memorandum of agreement or letter of intent signed by all parties that describes the parties'

roles, responsibilities and financial commitment in the proposed project.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (i) Be registered in SAM before submitting its application; (ii) provide a valid unique entity identifier in its application; and (iii) continue to maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by a Federal awarding agency. FTA may not make a Federal award to an applicant until the applicant has complied with all applicable unique entity identifier and SAM requirements and, if an applicant has not fully complied with the requirements by the time FTA is ready to make a Federal award, FTA may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making award to another applicant. Non-federal entities that have received a federal award are required to report certain civil, criminal, or administrative proceedings to SAM (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)) to ensure registration information is current and comply with federal requirements. Applicants should reference 2 CFR 200.113, for more information.

4. Submission Dates and Time

Project proposals must be submitted electronically through the *GRANTS.GOV* website at *http://www.Grants.GOV* by 11:59 p.m. Eastern time on May 10, 2021. Applications submitted after the deadline will not be accepted. Prospective applicants should initiate the process by registering on the *GRANTS.GOV* website promptly to ensure completion of the application process before the submission deadline.

FTA suggests applicants begin the registration process on *GRANTS.GOV* well in advance of the deadline and submit applications at least 72 hours prior to the deadline, to allow time to receive the validation messages and to correct any problems that may have caused a rejection notification. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website. Deadlines will not be extended due to scheduled website maintenance.

5. Funding Restrictions

Proposed projects under the TWC must provide direct support to public transit agency workforce development goals and objectives. Capital expenses such as equipment purchases are not considered to be eligible costs unless they directly relate to the workforce development program being supported by FTA funds. Acceptable costs can include but are not limited to faculty or instructors, technology and start-up costs for information technology systems and website resources, subject matter expert consultants in workforce development areas as needed, salaries and fringe benefits of direct staff, support staff, classroom space, books, materials and supplies, and transportation stipends for students.

The FTA funds under this program are not intended as an offset to regular transit agency employee salaries and may not be used to cover the regular or overtime salaries of employees at transit agencies offering training. Funds may be used to cover the costs of staff directly engaged in a program management or training role at an agency.

Funds under this NOFO cannot be used to reimburse projects for otherwise eligible expenses incurred prior to FTA award of a Grant Agreement or Cooperative Agreement unless FTA has issued a ''Letter of No Prejudice'' for the project before the expenses are incurred. Allowable direct and indirect expenses must be consistent with the Governmentwide Uniform Administrative Requirements and Cost Principles (2 CFR part 200) and FTA Circular 5010.1E.

6. Other Submission Requirements

Complete proposals for the Transit Workforce Center (TWC) must be submitted electronically through the GRANTS.GOV website by 11:59 p.m. Eastern time on May 10, 2021. Late applications will not be accepted. Once completed, the narrative application must be placed in the attachments section of the SF–424 Mandatory form. Applicants must attach the narrative application file to their submission in *GRANTS.GOV* to successfully complete the proposal process. A proposal submission may contain additional supporting documentation as attachments.

Applicants may submit more than one proposal. However, each proposal must not be duplicative. Submission of multiple proposals from a single entity will not increase that entity's chances of being awarded funding.

In addition to submittal in *GRANTS.GOV,* proposers are encouraged to begin the process of registration on the *GRANTS.GOV* website well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered proposers may still be required to take steps to keep their registration up to date before submissions can be made successfully: (1) Registration in the System for Award Management (SAM) (formerly the Central Contracting Registry (CCR) system) is required; and (2) persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions.

Within 24 to 48 hours after submitting an electronic application, the applicant should receive three email messages from *GRANTS.GOV:* (1) Confirmation of successful transmission to *GRANTS.GOV,* (2) confirmation of successful validation by *GRANTS.GOV,* and (3) confirmation of successful validation by FTA. If confirmations of successful validation are not received and a notice of failed validation or incomplete materials is received, the applicant must address the reasons for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reasons, include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission. FTA strongly encourages proposers to submit their applications at least 72 hours prior to the due date to allow time to receive the validation messages and to correct any problems that may have caused a rejection notification.

Eligible entities *must* have or must secure a DUNS number for the purposes of formal application and potential entry into a cooperative agreement with FTA. The DUNS number is a unique nine-character number that identifies your organization. It is a tool of the Federal government to track how Federal money is distributed. Each FTA applicant's DUNS number will be maintained as part of the applicant's profile. This number can be obtained free through the Dun and Bradstreet (D&B) website (*http://www.dnb.com/US/duns_update/*).

In addition, each entity that applies and does not have an exemption under 2 CFR 25.110 must:

- Be registered in the System for Award Management (SAM) prior to submitting an application or plan (*www.sam.gov*), and
- Maintain an active SAM registration with current information at all times during which it has an active Federal award or an application or plan under consideration by an agency.

E. Application Review Information

1. Criteria

FTA will assess the extent to which a proposal addresses the following criteria:

a. Innovation in Technical Assistance Provision—FTA will evaluate the extent to which an applicant identifies a unique or innovative approach in providing technical assistance to address workforce development issues in public transit.

b. Outreach, Marketing and Training Capacity for the Transit Workforce—FTA will evaluate whether an applicant's proposal demonstrates the ability to carry out outreach, marketing and training activities that focus on current and emerging transit workforce needs. Additionally, the applicant must be able to identify, develop, share and implement outreach, marketing and workforce training models.

c. Strategic Partnership Development—FTA will evaluate whether proposals demonstrate an ability to develop long-standing and strong transit workforce partnerships among current industry partners, new partners and within the Federal Government.

d. Project Management and Organizational Capacity—FTA will evaluate the capacity of the applicant and its required partners to effectively staff the proposed initiative and deliver the proposed outcomes, as well as the fiscal, administrative, and performance management capacity in implementing key components (*e.g.* technical assistance, outreach and marketing, etc.) of this project.

e. Promotion of Workforce Diversity and Equity—FTA will evaluate the extent to which the applicant demonstrates a dedication to and focus on furthering diversity and equity for transit workers.

f. Emphasis on Emerging Technology—FTA will evaluate the extent to which the applicant demonstrates a dedication to and focus on transit workforce development in emerging technology areas, including technologies relevant to responding to the climate crisis.

g. Sustainability of Center—FTA will evaluate the extent to which the applicants and required partners demonstrate a results-oriented approach to managing, operating and sustaining a technical assistance center after receiving initial FTA funding. In doing so, FTA will evaluate the track record of the applicants and its required partners, to implement projects of similar focus, size, and scope.

2. Review and Selection Process

A technical evaluation committee will review proposals under the project selection criteria. Members of the technical evaluation committee and the FTA Workforce Program Manager will screen each application for eligibility and rate the applications it receives, and may seek clarification from any applicant about any statement in its application that FTA finds ambiguous or to request additional documentation to be considered during the evaluation process to clarify information contained within the proposal. FTA may fund successful applications at up to 100 percent of project costs, and non-Federal matching contributions are not required. However, FTA may give priority consideration to applications that include non-Federal match. After consideration of the findings of the technical evaluation committee, the FTA Administrator will determine the final selection.

3. FAPIIS Check

FTA, prior to making a Federal award with a total amount of Federal share greater than the simplified acquisition threshold, is required to review and consider any information about the applicant that is in the designated integrity and performance system accessible through SAM (currently FAPIIS) (see 41 U.S.C. 2313). An applicant, at its option, may review information in the designated integrity and performance systems accessible through SAM and comment on any information about itself that a Federal awarding agency previously entered and is currently in the designated integrity and performance system accessible through SAM. FTA will consider any comments by the applicant, in addition to the other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in the Office of Management and Budget's Uniform Requirements for Federal Awards (2 CFR 200.206).

F. Federal Award Administration

1. Federal Award Notice

After the FTA Administrator has selected the proposal to be funded, the successful applicant will be notified by email or telephone of their status.

2. Administrative and National Policy Requirements

a. Notification of Award

Upon notification of intent to award funds, FTA may withdraw its offer to provide Federal assistance if the recipient does not provide a formal application consistent with its proposal submission within 90 days following the date of the offer.

b. Execution of the FTA Agreement

The successful applicant will be instructed by FTA on how to execute their cooperative agreement in FTA's electronic grants management system.

c. Start Date and Incurred Costs

Absent special circumstances, costs incurred prior to FTA award are not eligible as project expenses. The recipient may begin to incur project costs when the project is executed in FTA's Transit Award Management System (TrAMS). FTA expects recipients to implement the projects awarded as soon as possible and to fully expend grant funds during the period of performance, recognizing that full transparency and accountability are required for all expenditures.

d. Standard Assurances

Selected recipients must comply with all Federal statutes, regulations, executive orders, directives, FTA circulars, and other Federal administrative requirements in carrying out project supported activities by this FTA award. In addition to these requirements, recipients and sub-recipients of FTA funds are required to submit the Certifications and Assurances before entering into a grant or cooperative agreement, if there is no current certifications and assurances documents on file.

e. Statement of Work

Once selected for award, the recipient is asked to outline a plan of action, organized by work task, timelines, pertaining to the scope and detail of how the proposed work will be accomplished. List estimated milestone dates and performance measures/goals for major activities and products which are SMART—specific, measurable, achievable, relevant, and timebound. Activities should be justified in terms of eligible program activities and proposals should clearly demonstrate the connection between the planned work and at least one of the specific program activities cited. The Statement of Work also should address supporting activities, such as marketing plans for engaging participants and/or

dissemination strategies for sharing the results, if such are critical to the success of the supported program. There is a sense of urgency to set-up and implement this center, and FTA is dedicated to moving quickly once a final recipient is selected. Once selected, the applicant will have 60 days to work with the FTA assigned program manager to set-up, reserve and obligate the project within the FTA electronic grant making system. Applicants are encouraged to develop statements of work that can be easily edited and modified into a TrAMS application. This cooperative agreement will be managed from FTA's headquarters office.

Note: FTA, and any additional funding agencies, will participate in activities by negotiating the final statement of work, attending review meetings, commenting on technical reports, maintaining frequent contact with the project manager, approving key decisions and activities, and redirecting project activities, as needed.

Explain how your organization and the proposed partners' staff, systems, and experience will enable success in the development, implementation, and management of this new workforce development technical assistance center. Describe your specific approach, and how its innovative aspects have potential for nationwide or regional return on investments and sustainability. In addition to innovative workforce practices, cite the unique features of your services, such as design or technological innovations, reductions in cost or time, jobs created, new jobs facilitated, environmental benefits, internships/apprenticeships created, benefits to transit employees, or social and community involvement. Finally, identify uncertainties and external factors that could affect the schedule, cost, success, or sustainability of the Center. Supporting documentation may be provided as an attachment that will not count toward the total page limit.

f. Independent Evaluation

The selected recipient and its sub-recipients will be subject to evaluation by an independent evaluator selected and funded separately by FTA. Recipients will be required to coordinate with the independent evaluator to assist in developing an evaluation plan; and collecting, sorting, and managing data required to fulfill that evaluation plan, including providing documentation for all costs associated with the project.

g. Draft Workforce Metrics

The recipient funded here will be required to support efforts of FTA or its designee in the evaluation of the project and its outcomes against a set of workforce metrics.

h. Data Access & Data Sharing

Recipients funded under this announcement will be required to gather and share all relevant and required data with FTA within appropriate and agreed-upon timelines, to support any project evaluations.

In response to the White House Office of Science and Technology Policy memorandum, dated February 22, 2013, entitled ''Increasing Access to the Results of Federally Funded Scientific Research,'' the Department is incorporating Public Access requirements into all funding award (*e.g.* grants, cooperative agreements, etc.) for scientific research. Recipients are required to include these obligations in any-sub-awards or other related funding agreements.

Recipients must remove all Confidential Business Information (CBI) or PII information before providing public access to any project data. All appropriate data are to be accessible to FTA and/or the public for a minimum of five (5) years after the period of performance has expired.

Recipients and sub-recipients must make available to FTA copies of all work developed in performance of a project funded under this announcement, including but not limited to software and data.

i. Knowledge Transfer

Recipients and sub-recipients may be asked, during the period of performance, to participate in information exchange meetings, webinars, or outreach events to support FTA's goal of advancing models of success and information that is helping to address the critical workforce issues.

3. Reporting

Post-award reporting requirements include the electronic submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system. Applicant should include any goals, targets, and indicators referenced in their application in the Executive Summary of the TrAMS application.

As part of completing the annual certifications and assurances required of FTA recipients, a successful applicant must report on the suspension or debarment status of itself and its principals. If the award recipient's active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds $10,000,000 for any period of time during the period of performance of an award made pursuant to this Notice, the recipient must comply with the Recipient integrity and Performance Matters reporting requirements described in Appendix XII to 2 CFR part 200.

G. Federal Awarding Agency Contacts

If you have questions or need additional information about this Notice of Funding Opportunity, you may contact Ms. Betty Jackson by phone at 202.366.1730 or by email at *Betty.Jackson@dot.gov.* A TDD is available for individuals who are deaf or hard of hearing at 800.877.8339. Prospective applicants may visit the following websites for more information: *http://www.fta.dot.gov.*

For more on managing projects in accordance with FTA Circular 6100.1E: Transit Research and Technology Programs: Application Instructions and Program Management Guidelines: *https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/FTA_Cir_6100.1E.docx_4.08.2015_%282%29_0.pdf.* This Circular includes requirements on project management and administration including quarterly reporting, financial management, and payment.

For general program information, please use the contact information identified in the front of this notice. Please contact the *GRANTS.GOV* Helpdesk for assistance with electronic applications at *http://www.grants.gov.* You also may contact *support@grants.gov* or call toll-free (800.518.4726).

H. Other Supporting Information

a. FTA Annual Report on Technical Assistance and Workforce Development for FY 2018—*https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/research-innovation/132006/fta-annual-report-technical-assistnce-and-workforce-development-fy-2018-ftareportno0132_0.pdf.*

b. Advancing Frontline Workforce Development Meeting: Synthesis (Report 0154) (2018)—*https://www.transit.dot.gov/research-innovation/advancing-frontline-workforce-development-meeting-synthesis-report-0154.*

c. Innovative Transit Workforce Development Projects of 2015: Summative Evaluation (Report–0153)—*https://www.transit.dot.gov/research-innovation/innovative-transit-workforce-development-projects-2015-summative-evaluation.*

d. Innovative Transit Workforce Development Projects of 2012: Summative Evaluation—*https://www.transit.dot.gov/sites/fta.dot.gov/files/docs/research-innovation/130981/innovative-transit-workforce-development-projects-2012-summative-evaluation-fta-report-no0128_0.pdf*.

e. Innovative Transit Workforce Development Projects of 2011 Report (0094)—*https://www.transit.dot.gov/research-innovation/innovative-transit-workforce-development-projects-2011-report-report-0094*.

f. Innovative Transit Workforce Development Program: Key Lessons Learned (Report 0139)—*https://www.transit.dot.gov/research-innovation/innovative-transit-workforce-development-program-key-lessons-learned-report-0139*.

g. Transit Workforce Development: Improved Strategic Planning Practices Could Enhance FTA Efforts, GAO–19–290—*https://www.gao.gov/assets/700/697562.pdf*.

h. Summary of Workforce Development Summit Proceedings—*https://www.transit.dot.gov/research-innovation/summary-workforce-development-summit-proceedings-report-0096*.

i. All of FTA's Research Reports and Publications can be found here: *https://www.transit.dot.gov/research-innovation/fta-reports-and-publications*.

Nuria I. Fernandez,

Deputy Administrator.

[FR Doc. 2021–07749 Filed 4–14–21; 8:45 am]

BILLING CODE 4910–57–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2021–0027]

Agency Information Collection Activities; Notice and Request for Comment; National 911 Profile Database

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments on a request for extension of a currently-approved information collection.

SUMMARY: The National Highway Traffic Safety Administration (NHTSA) invites public comments about our intention to request approval from the Office of Management and Budget (OMB) for an extension of a currently-approved information collection. Before a Federal agency can collect certain information from the public, it must receive approval from OMB. Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections. This document describes a collection of information for which NHTSA intends to seek OMB approval on the National 911 Profile Database.

DATES: Comments must be submitted on or before June 14, 2021.

ADDRESSES: You may submit comments identified by the Docket No. NHTSA–2021–0027 through any of the following methods:

- *Electronic submissions:* Go to the Federal eRulemaking Portal at *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail or Hand Delivery:* Docket Management, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays. To be sure someone is there to help you, please call (202) 366–9322 before coming.

Instructions: All submissions must include the agency name and docket number for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below.

Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit *https://www.transportation.gov/privacy.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the street address listed above. Follow the online instructions for accessing the dockets via internet.

FOR FURTHER INFORMATION CONTACT: For additional information or access to background documents, contact Ms. Laurie Flaherty, Coordinator, National 911 Program, Office of Emergency Medical Services, National Highway Traffic Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, NPD–400, Room W44–322, Washington, DC 20590. Ms. Flaherty's phone number is (202) 366–2705 and her email address is *laurie.flaherty@dot.gov.* Please identify the relevant collection of information by referring to its OMB Control Number.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), before an agency submits a proposed collection of information to OMB for approval, it must first publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulation (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) how to enhance the quality, utility, and clarity of the information to be collected; (d) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.* permitting electronic submission of responses. In compliance with these requirements, NHTSA asks for public comments on the following proposed collection of information for which the agency is seeking approval from OMB.

Title: National 911 Profile Database.

OMB Control Number: 2127–0679.

Type of Request: Request for extension of a currently-approved information collection.

Type of Review Requested: Regular

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information: The National 911 Program is housed within NHTSA's Office of Emergency Medical Services, which has a mission to provide coordination in assessing, planning, developing, and promoting comprehensive, evidence-based emergency medical services and 911 systems. Pursuant to 47 U.S.C. 942, Coordination of 911, E911, and Next

Generation 911 implementation, the National 911 Program exists to coordinate 911 efforts, collect and create resources for State and local 911 agencies, and to oversee a grant program, specifically to upgrade the nation's outdated 911 infrastructure.

NHTSA is requesting an extension of its information collection, carried out under 47 U.S.C. 942 (a)(3)(B), to continue to collect and aggregate information from State-level reporting entities that can be used to measure the progress of 911 authorities across the country in upgrading and enhancing their existing operations and migrating to more advanced—digital, internet-Protocol-enabled—emergency networks. The data will be maintained in a ''National 911 Profile Database.'' The National 911 Profile Database maintains State-specific and benchmarking data, which is later analyzed by the 911 Program for trends and findings. Collecting and sharing nationwide 911 statistics helps the 911 community better understand the state of the industry. The National 911 Profile Database enables voluntary submission of data by State and territorial 911 agencies via annual data submission. The information to be collected includes data useful for evaluating the status of 911 programs across the country, along with their progress in implementing upgraded and advanced systems and capabilities. The data elements involved will fall within two major categories: baseline and progress benchmarks.

- ''Baseline'' data elements reflect the current status and nature of 911 operations from State to State. These elements are largely descriptive in nature, are intended to provide a general view of existing 911 services across the country, and are grouped within five categories: Total 911 Calls and Call Type, Number of Public Safety Answering Points (PSAPs) and Equipment Positions, Emergency Medical Dispatch and Operations, Call-Handling Quality Assurance, and Minimum Training Requirements.
- ''Progress benchmarks'' reflect the status of State efforts to implement advanced next generation 911 systems and capabilities. As titled, these data elements are largely implementation or deployment benchmarks against which progress can be measured, and include: Planning, Procurement, Transition, Operations, and Maturity Level.

Description of the Need for the Information and Proposed Use of the Information:

To support NHTSA's mission to save lives, the National 911 Program develops, collects, and disseminates information concerning practices, procedures, and technology used in the provision of 911 services; and to support 911 Public Safety Answering Points (PSAPs) and related State and local public safety agencies' 911 technological and operational upgrades.

The technology impacting 911 services continues to evolve substantially. Both public and private sectors have increasingly focused on addressing the need to upgrade and enhance the technology utilized by 911 services across the Nation. In addition, it is essential that emergency responders are able to coordinate and collaborate with 911 agencies via comprehensive and seamless emergency communication systems as they update their own part of the emergency communications network. This information collection supports efforts to upgrade 911 services by providing up-to-date information to State and local public safety entities to allow them to adequately gauge progress towards implementing more current and advanced 911 systems in a comparative fashion. While the National 911 Program will benefit from this information, it is anticipated that the greatest benefit will accrue to the State and local public safety community faced with the challenge of migrating to the next generation of 911 services and technology as they strive to respond to emergencies.

The National 911 Profile Database is used to follow the progress of 911 authorities in enhancing their existing systems and implementing next-generation networks to more current functionality. The data in this national profile has been used and will continue to be used to accurately measure and depict the current status and capabilities of 911 systems across the United States, as well as progress made in implementing advanced technologies and operations—known as Next Generation (NG) 911. Assessments, based upon the data collected, will help draw attention to key roadblocks as well as solutions in NG911 implementation processes. Analysis of the data will also help target possible future activities and resources consistent with the goals of the program. The information collected will be available in aggregated form to national, Federal, State and local stakeholders in the public safety community. This information collection supports NHTSA's mission to save lives, prevent injuries and reduce economic costs due to road traffic crashes by ensuring emergency responses to crashes of all nature (*e.g.* planes, trains, and automobiles) and maximizing the chances of survival for crash victims.

Affected Public: State 911 agency administrators.

Estimated Number of Respondents: Maximum number of responses: 56.

Frequency: Annual.

Number of Responses: Maximum number of responses: 56.

Estimated Total Annual Burden Hours: NHTSA estimates that submitting responses to the questions included in the proposed survey instrument utilizing the Web-based tool would require an average of 98 hours per State entity to collect, aggregate and submit. Estimating the maximum number of respondents at 56 (the fifty States, the District of Columbia, and five U.S. Territories), this would result in a total burden of 5,488 hours (98 hours × 56 respondents).

The total labor costs associated with the burden hours are estimated by finding the average hourly wage and multiplying by the number of burden hours. Respondents will be State, territory, and tribal government management personnel. To estimate reasonable staff expenses to respond to this information collection, the Agencies reviewed the Bureau of Labor Statistics (BLS) Occupational Outlook Handbook and determined that the Administrative Services Manager description closely aligns with the positions of recipient staff responsible for completing this request. BLS lists the average hourly wage as $46.45.[1] Further, BLS estimates that State and local government wages represent 61.8% of total labor compensation costs.[2] Therefore, NHTSA estimates the hourly labor costs to be $75.16 (46.45 ÷ 0.618). The total labor cost based on the estimated burden hours is estimated at $412,478. The table below provides a summary of the estimated burden hours and the labor costs associated with those burden hours.

[1] May 2019 National Occupational Employment and Wage Estimates by ownership, Federal, State, and local government, including government-owned schools and hospitals and the U.S. Postal Service, at *https://www.bls.gov/oes/current/999001.htm#11-0000* (BLS code 11–3010).

[2] Table 1 at *https://www.bls.gov/news.release/ecec.t01.htm.*

Number of respondents	Annual hours per respondent	Average hourly compensation	Estimated annual labor cost per respondent	Total estimated annual burden hours	Total estimated annual labor costs
56	98	75.16	$7,365.68	5,488	$412,478.08 or $412,478

Estimated Total Annual Burden Cost: There are no capital, start-up, or annual operation and maintenance costs involved in the collection of information. The respondents would not incur any reporting costs from the information collection beyond the labor costs associated with the burden hours to gather the information, prepare it for reporting and then populate the Web-based data collection tool. The respondents also would not incur any recordkeeping burden or recordkeeping costs from the information collection.

Public Comments Invited: You are asked to comment on any aspects of this information collection, including (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (b) the accuracy of the Department's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; 49 CFR 1.49; and DOT Order 1351.29.

Issued in Washington, DC.

Nanda Narayanan Srinivasan,

Associate Administrator, Research and Program Development.

[FR Doc. 2021–06974 Filed 4–14–21; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Government Securities Act of 1986

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. Currently, the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the collection of information associated with the Government Securities Act (GSA) of 1986, as amended (15 U.S.C. 78o–5).

DATES: Written comments should be received on or before June 14, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Lori Santamorena, Government Securities Regulations Staff, Bureau of the Fiscal Service, (202) 504–3632, *govsecreg@fiscal.treasury.gov*.

SUPPLEMENTARY INFORMATION:

Title: Government Securities Act of 1986, as amended, (15 U.S.C. 78o–5).

OMB Number: 1530–0064.

Abstract: The information collection is contained within the regulations issued pursuant to the GSA, which require government securities brokers and dealers to make and keep certain records concerning their business activities and their holdings of government securities, to submit financial reports, and to make certain disclosures to investors. The regulations also require depository institutions to keep certain records of non-fiduciary custodial holdings of government securities. The regulations and associated information collection are fundamental to customer protection and dealer financial responsibility.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Private Sector (Government securities brokers and dealers and financial institutions).

Estimated Number of Respondents: 2,670.

Estimated Total Annual Burden Hours: 215,111.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 12, 2021.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2021–07703 Filed 4–14–21; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 3491

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning Form 3491, Consumer Cooperative Exemption Application.

DATES: Written comments should be received on or before June 14, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington, (737) 800–6149, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Consumer Cooperative Exemption Application.

OMB Number: 1545–1941.

Form Number: Form 3491.

Abstract: A cooperative uses Form 3491 to apply for exemption from filing Form 1099–PATR, Taxable Distributions received from Cooperatives. Form 1099–PATR is used to report patronage distributions of $10 or more to a recipient during the calendar year.

Current Actions: There are no changes being made to the Form 3491 at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit, Individuals or households, and Farms.

Estimated Number of Respondents: 200.

Estimated Time per Respondent: 44 minutes.

Estimated Total Annual Burden Hours: 148.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Requests for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 6, 2021.

Sara L. Covington,

IRS Tax Analyst.

[FR Doc. 2021–07748 Filed 4–14–21; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Extension of Information Collection Request Submitted for Public Comment; Comment Request on Burden Related to Information Collection Tools Relating to IRS Customer Satisfaction Surveys

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently, the IRS is soliciting comments concerning the burden related to the IRS Customer Satisfaction Surveys.

DATES: Written comments should be received on or before June 14, 2021 to be assured of consideration.

ADDRESSES: Direct all written comments to Kinna Brewington, Internal Revenue Service, Room 6529, 1111 Constitution Avenue NW, Washington, DC 20224. Requests for additional information or copies of the regulations should be directed to R. Joseph Durbala, at Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *RJoseph.Durbala@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: IRS Customer Satisfaction Surveys.

OMB Number: 1545–2250.

Regulation Project Number: N/A.

Abstract: Surveys conducted under this clearance are used by the Internal Revenue Service to determine levels of customer satisfaction as well as determining issues that contribute to customer burden. This information will be used to make quality improvements to products and services. Collecting, analyzing, and using customer opinion data is a vital component of IRS's Balanced Measures Approach, as mandated by Internal Revenue Service Reform and Restructuring Act of 1998 and Executive Order 12862.

Current Actions: This is a renewal request. The change in burden is the result of 10 surveys being dropped from this renewal. It is estimated that 60,000 burden hours will be used over the course of the next three years.

Type of Review: Revision of a currently approved collection.

Affected Public: Individuals or households, Businesses and other for-profit organizations.

Estimated Number of Responses: 135,000.

Estimated Time per Respondent: 8–9 mins.

Estimated Total Annual Burden Hours: 20,000.

The following paragraph applies to all the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Desired Focus of Comments: The Internal Revenue Service (IRS) is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* by permitting electronic submissions of responses.

Comments submitted in response to this notice will be summarized and/or included in the ICR for OMB approval of the extension of the information collection; they will also become a matter of public record.

Approved: April 6, 2021.

Ronald J. Durbala,

IRS Tax Analyst.

[FR Doc. 2021–07751 Filed 4–14–21; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413 and 489

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 413, and 489

[CMS–1746–P]

RIN 0938–AU36

Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal Fiscal Year 2022

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would update the payment rates used under the prospective payment system (PPS) for skilled nursing facilities (SNFs) for fiscal year (FY) 2022. In addition, the proposed rule includes a proposed forecast error adjustment for FY 2022, proposes updates to the diagnosis code mappings used under the Patient Driven Payment Model (PDPM), proposes to rebase and revise the SNF market basket, proposes to implement a recently-enacted SNF consolidated billing exclusion along with the required proportional reduction in the SNF PPS base rates, and includes a discussion of a methodology to recalibrate the PDPM parity adjustment. In addition, the proposed rule includes proposals for the SNF Quality Reporting Program (QRP) and the SNF Value-Based Purchasing (VBP) Program, including a proposal to suppress the use of the SNF readmission measure for scoring and payment adjustment purposes in the FY 2022 SNF VBP program because we have determined that circumstances caused by the public health emergency for COVID–19 have significantly affected the validity and reliability of the measure and resulting performance scores.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on June 7, 2021.

ADDRESSES: In commenting, please refer to file code CMS–1746–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1746–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1746–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Penny Gershman, (410) 786–6643, for information related to SNF PPS clinical issues.

Anthony Hodge, (410) 786–6645, for information related to consolidated billing, and payment for SNF-level swing-bed services.

John Kane, (410) 786–0557, for information related to the development of the payment rates and case-mix indexes, and general information.

Kia Burwell, (410) 786–7816, for information related to the wage index.

Heidi Magladry, (410) 786–6034, for information related to the skilled nursing facility quality reporting program.

Lang Le, (410) 786–5693, for information related to the skilled nursing facility value-based purchasing program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

As discussed in the FY 2014 SNF PPS final rule (78 FR 47936), tables setting forth the Wage Index for Urban Areas Based on CBSA Labor Market Areas and the Wage Index Based on CBSA Labor Market Areas for Rural Areas are no longer published in the **Federal Register**. Instead, these tables are available exclusively through the internet on the CMS website. The wage index tables for this proposed rule can be accessed on the SNF PPS Wage Index home page, at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Readers who experience any problems accessing any of these online SNF PPS wage index tables should contact Kia Burwell at (410) 786–7816.

To assist readers in referencing sections contained in this document, we are providing the following Table of Contents.

Table of Contents

I. Executive Summary

A. Purpose

This proposed rule would update the SNF prospective payment rates for fiscal year (FY) 2022 as required under section 1888(e)(4)(E) of the Social Security Act (the Act). It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication of certain specified information relating to the payment update (see section II.C. of this proposed rule) in the **Federal Register**, before the August 1 that precedes the start of each FY. As discussed in section V.A. of this proposed rule, it would also rebase and revise the SNF market basket index, including updating the base year from 2014 to 2018. As discussed in section IV.D. of this proposed rule, it would also make revisions in the regulation text to exclude from SNF consolidated billing certain blood clotting factors and items and services related to the furnishing of such factors effective for items and services furnished on or after October 1, 2021, as required by the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, enacted December 27, 2020), as well as certain other conforming revisions. In addition, as required under section 1888(e)(4)(G)(iii) of the Act, as added by section 103(b) of the BBRA 1999, we propose to provide for a proportional reduction in the Part A SNF PPS base rates to account for this exclusion, as described in section III.B.6. of this proposed rule. We also propose to make changes to the code mappings used under the SNF PPS for classifying patients into case-mix groups. Additionally, this proposed rule includes a proposed forecast error adjustment for FY 2022. This proposed rule also includes a discussion of a methodology to recalibrate the PDPM parity adjustment. Finally, this proposed rule would also update requirements for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) and the Skilled Nursing Facility Value-Based Purchasing Program (SNF VBP), including a proposal to suppress the use of the SNF readmission measure for scoring and payment adjustment purposes in the FY 2022 SNF VBP program because we have determined that circumstances caused by the public health emergency for COVID–19 have significantly affected the validity and reliability of the measure and resulting performance scores.

B. Summary of Major Provisions

In accordance with sections 1888(e)(4)(E)(ii)(IV) and (e)(5) of the Act, the Federal rates in this proposed rule would reflect an update to the rates that we published in the SNF PPS final rule for FY 2021 (85 FR47594, August 5, 2020). We also propose to rebase and revise the SNF market basket index, including updating the base year from 2014 to 2018. This proposed rule proposes revisions to the regulation text to exclude from SNF consolidated billing certain blood clotting factors and items and services related to the furnishing of such factors effective for items and services furnished on or after October 1, 2021, as required by the Consolidated Appropriations Act, 2021, as well as certain conforming revisions. We also propose to make a required reduction in the SNF PPS base rates to account for this new exclusion. This proposed rule also proposes revisions to the International Classification of Diseases, Version 10 (ICD–10) code mappings used under PDPM to classify patients into case-mix groups. Additionally, this proposed rule includes a proposed forecast error adjustment for FY 2022. This proposed rule also includes a discussion of a methodology to recalibrate the PDPM parity adjustment, used to implement PDPM in a budget neutral manner.

This proposed rule proposes to update requirements for the SNF QRP, including the proposal of two new quality measures beginning with the FY 2023 SNF QRP: The SNF Healthcare Associated Infections (HAI) Requiring Hospitalization measure; and the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure. We are proposing that SNFs use the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN) as the method of data submission for the proposed COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure. We are also proposing to modify the denominator for the Transfer of Health Information to the Patient—Post Acute Care (PAC) Measure. We are proposing a revision to the number of quarters used for publicly reporting certain SNF QRP measures due to the public health emergency (PHE). Finally, we are seeking comment on the use of Health Level Seven International (HL7®) Fast Healthcare Interoperability Resources® (FHIR) in quality programs, specifically the SNF QRP, and on our continued efforts to close the health equity gap.

Additionally, we are proposing several updates for the SNF VBP Program including a proposal to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2022 SNF VBP Program Year and other proposals for scoring and adjusting payments to SNFs for that program year if the SNFRM is suppressed. We are also proposing to update the Phase One Review and Corrections policy to implement a claims ''snapshot'' policy which would align the review and corrections policy for the SNF VBP Program with the review and corrections policy we use in other value-based purchasing programs and to codify the proposed policy at § 413.338(e)(1) of our regulations. We are further proposing to make a technical update to the instructions for a SNF to request an extraordinary circumstance exception and to codify that update at § 413.338(d)(4)(ii) of our regulations. Finally, we are seeking comments on measures and measure concepts we are considering for an expanded SNF VBP Program measure set.

C. Summary of Cost and Benefits

TABLE 1—COST AND BENEFITS

Provision description	Total transfers/costs
Proposed FY 2022 SNF PPS payment rate update.	The overall economic impact of this proposed rule is an estimated increase of $444 million in aggregate payments to SNFs during FY 2022.
Proposed FY 2022 SNF QRP changes	The overall economic impact of this proposed rule is an estimated increase in cost to SNFs of $6.63 million.
Proposed FY 2022 SNF VBP changes	The overall economic impact of the SNF VBP Program is an estimated reduction of $191.64 million in aggregate payments to SNFs during FY 2022.

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) (*https://pacioproject.org/*) to facilitate collaboration with industry stakeholders to develop FHIR standards. These standards could support the exchange and reuse of patient assessment data derived from the minimum data set (MDS), inpatient rehabilitation facility patient assessment instrument (IRF–PAI), long term care hospital continuity assessment record and evaluation (LCDS), outcome and assessment information set (OASIS), and other sources. The PACIO Project has focused on FHIR implementation guides for functional status, cognitive status and new use cases on advance directives and speech, and language pathology. We encourage post-acute care (PAC) provider and health information technology (IT) vendor participation as these efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as the authoritative resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED). The DEL furthers CMS' goal of data standardization and interoperability. When combined with digital information systems that capture and maintain these coded elements, their standardized clinical content can reduce provider burden by supporting and exchange of standardized healthcare data; supporting provider exchange of electronic health information for care coordination, person-centered care; and supporting real-time, data driven, clinical decision making. Standards in the Data Element Library (*https://del.cms.gov/DELWeb/pubHome*) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2021 ISA is available at *https://www.healthit.gov/isa.*

The 21st Century Cures Act (Cures Act) (Pub. L. 114–255, enacted December 13, 2016) requires HHS to take new steps to enable the electronic sharing of health information ensuring interoperability for providers and settings across the care continuum. The Cures Act includes a trusted exchange framework and common agreement (TEFCA) provision [1] that will enable the nationwide exchange of electronic health information across health information networks and provide an important way to enable bi-directional health information exchange in the future. For more information on current developments related to TEFCA, we refer readers to *https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement* and *https://rce.sequoiaproject.org/.*

The ONC final rule entitled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (85 FR 25642) published in the May 1, 2020 **Federal Register** (hereinafter referred to as ''ONC Cures Act Final Rule'') established policies related to information blocking as authorized under section 4004 of the 21st Century Cures Act. Information blocking is generally defined as a practice by a health IT developer of certified health IT, health information network, health information exchange, or health care provider that, except as required by law or specified by the HHS Secretary as a reasonable and necessary activity, is likely to interfere with access, exchange, or use of electronic health information. The definition of information blocking includes a knowledge standard, which is different for health care providers than for health IT developers of certified health IT and health information networks or health information exchanges. A healthcare provider must know that the practice is unreasonable, as well as likely to interfere with access, exchange, or use of electronic health information. To deter information blocking, health IT developers of certified health IT, health information networks and health information exchanges whom the HHS Inspector General determines, following an investigation, have committed information blocking, are subject to civil monetary penalties of up to $1 million per violation. Appropriate disincentives for health care providers are expected to be established by the Secretary through future rulemaking. Stakeholders can learn more about information blocking at *https://www.healthit.gov/curesrule/final-rule-policy/information-blocking.* ONC has posted information resources including fact sheets (*https://www.healthit.gov/curesrule/resources/fact-sheets*), frequently asked questions (*https://www.healthit.gov/curesrule/resources/information-blocking-faqs*), and recorded webinars (*https://www.healthit.gov/curesrule/resources/webinars*).

We invite providers to learn more about these important developments and how they are likely to affect SNFs.

[1] ONC, Draft 2 Trusted Exchange Framework and Common Agreement, *https://www.healthit.gov/sites/default/files/page/2019-04/FINAL TEFCAQTF41719508version.pdf.*

II. Background on SNF PPS

A. Statutory Basis and Scope

As amended by section 4432 of the Balanced Budget Act of 1997 (BBA 1997) (Pub. L. 105–33, enacted August 5, 1997), section 1888(e) of the Act provides for the implementation of a PPS for SNFs. This methodology uses prospective, case-mix adjusted per diem payment rates applicable to all covered SNF services defined in section 1888(e)(2)(A) of the Act. The SNF PPS is effective for cost reporting periods beginning on or after July 1, 1998, and covers all costs of furnishing covered SNF services (routine, ancillary, and capital-related costs) other than costs associated with approved educational activities and bad debts. Under section 1888(e)(2)(A)(i) of the Act, covered SNF services include post-hospital extended care services for which benefits are provided under Part A, as well as those items and services (other than a small number of excluded services, such as physicians' services) for which payment may otherwise be made under Part B and which are furnished to Medicare beneficiaries who are residents in a SNF during a covered Part A stay. A comprehensive discussion of these provisions appears in the May 12, 1998 interim final rule (63 FR 26252). In addition, a detailed discussion of the legislative history of the SNF PPS is available online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.*

Section 215(a) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014) added section 1888(g) to the Act requiring the Secretary to specify an all-cause all-condition hospital readmission measure and an all-condition risk-adjusted potentially preventable hospital readmission measure for the SNF setting. Additionally, section 215(b) of PAMA added section 1888(h)

to the Act requiring the Secretary to implement a VBP program for SNFs. Finally, section 2(c)(4) of the IMPACT Act amended section 1888(e)(6) of the Act, which requires the Secretary to implement a QRP for SNFs under which SNFs report data on measures and resident assessment data.

B. Initial Transition for the SNF PPS

Under sections 1888(e)(1)(A) and (e)(11) of the Act, the SNF PPS included an initial, three-phase transition that blended a facility-specific rate (reflecting the individual facility's historical cost experience) with the Federal case-mix adjusted rate. The transition extended through the facility's first 3 cost reporting periods under the PPS, up to and including the one that began in FY 2001. Thus, the SNF PPS is no longer operating under the transition, as all facilities have been paid at the full Federal rate effective with cost reporting periods beginning in FY 2002. As we now base payments for SNFs entirely on the adjusted Federal per diem rates, we no longer include adjustment factors under the transition related to facility-specific rates for the upcoming FY.

C. Required Annual Rate Updates

Section 1888(e)(4)(E) of the Act requires the SNF PPS payment rates to be updated annually. The most recent annual update occurred in a final rule that set forth updates to the SNF PPS payment rates for FY 2021 (85 FR 47594, August 5, 2020).

Section 1888(e)(4)(H) of the Act specifies that we provide for publication annually in the **Federal Register** the following:

- The unadjusted Federal per diem rates to be applied to days of covered SNF services furnished during the upcoming FY.
- The case-mix classification system to be applied for these services during the upcoming FY.
- The factors to be applied in making the area wage adjustment for these services.

Along with other revisions discussed later in this preamble, this proposed rule provides the required annual updates to the per diem payment rates for SNFs for FY 2022.

III. Proposed SNF PPS Rate Setting Methodology and FY 2022 Update

A. Federal Base Rates

Under section 1888(e)(4) of the Act, the SNF PPS uses per diem Federal payment rates based on mean SNF costs in a base year (FY 1995) updated for inflation to the first effective period of the PPS. We developed the Federal payment rates using allowable costs from hospital-based and freestanding SNF cost reports for reporting periods beginning in FY 1995. The data used in developing the Federal rates also incorporated a Part B add-on, which is an estimate of the amounts that, prior to the SNF PPS, would be payable under Part B for covered SNF services furnished to individuals during the course of a covered Part A stay in a SNF.

In developing the rates for the initial period, we updated costs to the first effective year of the PPS (the 15-month period beginning July 1, 1998) using a SNF market basket index, and then standardized for geographic variations in wages and for the costs of facility differences in case mix. In compiling the database used to compute the Federal payment rates, we excluded those providers that received new provider exemptions from the routine cost limits, as well as costs related to payments for exceptions to the routine cost limits. Using the formula that the BBA 1997 prescribed, we set the Federal rates at a level equal to the weighted mean of freestanding costs plus 50 percent of the difference between the freestanding mean and weighted mean of all SNF costs (hospital-based and freestanding) combined. We computed and applied separately the payment rates for facilities located in urban and rural areas, and adjusted the portion of the Federal rate attributable to wage-related costs by a wage index to reflect geographic variations in wages.

B. SNF Market Basket Update

1. SNF Market Basket Index

Section 1888(e)(5)(A) of the Act requires us to establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we rebased and revised the market basket index, which included updating the base year from FY 2010 to 2014. In this year's rule, we propose to rebase and revise the market basket index and update the base year from 2014 to 2018. See section V.A. of this proposed rule for more information.

The SNF market basket index is used to compute the market basket percentage change that is used to update the SNF Federal rates on an annual basis, as required by section 1888(e)(4)(E)(ii)(IV) of the Act. This market basket percentage update is adjusted by a forecast error correction, if applicable, and then further adjusted by the application of a productivity adjustment as required by section 1888(e)(5)(B)(ii) of the Act and described in section III.B.2.d. of this proposed rule. In the FY 2021 SNF PPS final rule (85 FR 47597), the SNF market basket percentage was estimated to be 2.2 percent for FY 2021 based on IHS Global Inc's (IGI's) second quarter 2020 forecast of the 2014-based SNF market basket with historical data through first quarter 2020.

For this proposed rule, we propose a FY 2022 SNF market basket percentage of 2.3 percent based on IGI's fourth quarter 2020 forecast of the proposed 2018-based SNF market basket (before application of the forecast error adjustment and multifactor productivity (MFP) adjustment). We also propose that if more recent data subsequently become available (for example, a more recent estimate of the market basket and/or the MFP), we would use such data, if appropriate, to determine the FY 2022 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or MFP adjustment in the SNF PPS final rule.

In section III.B.2.e. of this proposed rule, we discuss the 2 percent reduction applied to the market basket update for those SNFs that fail to submit measures data as required by section 1888(e)(6)(A) of the Act.

2. Use of the SNF Market Basket Percentage

Section 1888(e)(5)(B) of the Act defines the SNF market basket percentage as the percentage change in the SNF market basket index from the midpoint of the previous FY to the midpoint of the current FY. For the Federal rates set forth in this proposed rule, we use the percentage change in the SNF market basket index to compute the update factor for FY 2022. This factor is based on the FY 2022 percentage increase in the proposed 2018-based SNF market basket index reflecting routine, ancillary, and capital-related expenses. As stated previously, in this proposed rule, the SNF market basket percentage update is estimated to be 2.3 percent for FY 2022 based on IGI's fourth quarter 2020 forecast.

3. Forecast Error Adjustment

As discussed in the June 10, 2003 supplemental proposed rule (68 FR 34768) and finalized in the August 4, 2003 final rule (68 FR 46057 through 46059), § 413.337(d)(2) provides for an

adjustment to account for market basket forecast error. The initial adjustment for market basket forecast error applied to the update of the FY 2003 rate for FY 2004, and took into account the cumulative forecast error for the period from FY 2000 through FY 2002, resulting in an increase of 3.26 percent to the FY 2004 update. Subsequent adjustments in succeeding FYs take into account the forecast error from the most recently available FY for which there is final data, and apply the difference between the forecasted and actual change in the market basket when the difference exceeds a specified threshold. We originally used a 0.25 percentage point threshold for this purpose; however, for the reasons specified in the FY 2008 SNF PPS final rule (72 FR 43425), we adopted a 0.5 percentage point threshold effective for FY 2008 and subsequent FYs. As we stated in the final rule for FY 2004 that first issued the market basket forecast error adjustment (68 FR 46058), the adjustment will reflect both upward and downward adjustments, as appropriate.

For FY 2020 (the most recently available FY for which there is final data), the forecasted or estimated increase in the SNF market basket index was 2.8 percentage points, and the actual increase for FY 2020 is 2.0 percentage points, resulting in the actual increase being 0.8 percentage point lower than the estimated increase. Accordingly, as the difference between the estimated and actual amount of change in the market basket index exceeds the 0.5 percentage point threshold, under the policy previously described (comparing the forecasted and actual increase in the market basket), the FY 2022 market basket percentage change of 2.3 percent would be adjusted downward to account for the forecast error correction of 0.8 percentage point, resulting in a SNF market basket percentage change of 1.5 percent.

We note that we may consider modifying this forecast error methodology in future rulemaking. We invite comments and feedback on this issue, in particular on the possibility of, in future rulemaking, either eliminating the forecast error adjustment, or raising the threshold for the forecast error from 0.5 percent to 1.0 percent.

Table 2 shows the forecasted and actual market basket increases for FY 2020.

TABLE 2—DIFFERENCE BETWEEN THE ACTUAL AND FORECASTED MARKET BASKET INCREASES FOR FY 2020

Index	Forecasted FY 2020 Increase*	Actual FY 2020 Increase**	FY 2020 difference
SNF	2.8	2.0	−0.8

* Published in **Federal Register**; based on second quarter 2019 IGI forecast (2014-based index).
** Based on the fourth quarter 2020 IGI forecast (2014-based index).

4. Multifactor Productivity Adjustment

Section 1888(e)(5)(B)(ii) of the Act, as added by section 3401(b) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148, enacted March 23, 2010) requires that, in FY 2012 and in subsequent FYs, the market basket percentage under the SNF payment system (as described in section 1888(e)(5)(B)(i) of the Act) is to be reduced annually by the MFP adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, in turn, defines the MFP adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost-reporting period, or other annual period). The Bureau of Labor Statistics (BLS) is the agency that publishes the official measure of private nonfarm business MFP. We refer readers to the BLS website at *http://www.bls.gov/mfp* for the BLS historical published MFP data.

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projections of the components of MFP are currently produced by IGI, a nationally recognized economic forecasting firm with which CMS contracts to forecast the components of the market baskets and MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS, using a series of proxy variables derived from IGI's U.S. macroeconomic models. For a discussion of the MFP projection methodology, we refer readers to the FY 2012 SNF PPS final rule (76 FR 48527 through 48529) and the FY 2016 SNF PPS final rule (80 FR 46395). A complete description of the MFP projection methodology is available on our website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.*

a. Incorporating the MFP Into the Market Basket Update

Per section 1888(e)(5)(A) of the Act, the Secretary shall establish a SNF market basket index that reflects changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Section 1888(e)(5)(B)(ii) of the Act, added by section 3401(b) of the Affordable Care Act, requires that for FY 2012 and each subsequent FY, after determining the market basket percentage described in section 1888(e)(5)(B)(i) of the Act, the Secretary shall reduce such percentage by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (which we refer to as the MFP adjustment). Section 1888(e)(5)(B)(ii) of the Act further states that the reduction of the market basket percentage by the MFP adjustment may result in the market basket percentage being less than zero for a FY, and may result in payment rates under section 1888(e) of the Act being less than such payment rates for the preceding fiscal year. Thus, if the application of the MFP adjustment to the market basket percentage calculated under section 1888(e)(5)(B)(i) of the Act results in an MFP-adjusted market basket percentage that is less than zero, then the annual update to the unadjusted Federal per diem rates under section 1888(e)(4)(E)(ii) of the Act would be negative, and such rates would decrease relative to the prior FY.

Based on the data available for this FY 2022 SNF PPS proposed rule, the current estimate of the 10-year moving average of changes in MFP for the period ending September 30, 2022 would be 0.2 percentage point.

Consistent with section 1888(e)(5)(B)(i) of the Act and § 413.337(d)(2), as discussed previously, the market basket percentage for FY 2022 for the SNF PPS is based on IGI's fourth quarter 2020 forecast of the SNF market basket percentage, which is estimated to be 2.3 percent. As discussed above, we are applying a 0.2 percentage point MFP adjustment to the FY 2022 SNF market basket percentage.

The resulting MFP-adjusted FY 2022 SNF market basket update is, therefore, equal to 2.1 percent, or 2.3 percent less 0.2 percentage point.

5. Market Basket Update Factor for FY 2022

Sections 1888(e)(4)(E)(ii)(IV) and (e)(5)(i) of the Act require that the update factor used to establish the FY 2022 unadjusted Federal rates be at a level equal to the market basket index percentage change. Accordingly, we determined the total growth from the average market basket level for the period of October 1, 2020 through September 30, 2021 to the average market basket level for the period of October 1, 2021 through September 30, 2022. This process yields a percentage change in the proposed 2018-based SNF market basket of 2.3 percent.

As further explained in section III.B.2.c. of this proposed rule, as applicable, we adjust the market basket percentage change by the forecast error from the most recently available FY for which there is final data and apply this adjustment whenever the difference between the forecasted and actual percentage change in the market basket exceeds a 0.5 percentage point threshold. Since the forecasted FY 2020 SNF market basket percentage change exceeded the actual FY 2020 SNF market basket percentage change (FY 2020 is the most recently available FY for which there is historical data) by more than the 0.5 percentage point threshold, we propose to adjust the FY 2022 market basket percentage change downward by the forecast error correction. Applying the −0.8 percent forecast error correction results in an adjusted FY 2022 SNF market basket percentage change of 1.5 percent (2.3 percent market basket update less 0.8 percentage point forecast error adjustment).

Section 1888(e)(5)(B)(ii) of the Act requires us to reduce the market basket percentage change by the MFP adjustment (10-year moving average of changes in MFP for the period ending September 30, 2022) which is estimated to be 0.2 percent, as described in section III.B.2.d. of this proposed rule. Thus, we propose to apply a net SNF market basket update factor of 1.3 percent in our determination of the FY 2022 SNF PPS unadjusted Federal per diem rates, which reflects a market basket increase factor of 2.3 percent, less the 0.8 percent forecast error correction and less the projected 0.2 percentage point MFP adjustment.

We note that if more recent data become available (for example, a more recent estimate of the SNF market basket and/or MFP), we would use such data, if appropriate, to determine the FY 2022 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or MFP adjustment in the FY 2022 SNF PPS final rule.

We also note that section 1888(e)(6)(A)(i) of the Act provides that, beginning with FY 2018, SNFs that fail to submit data, as applicable, in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for a fiscal year will receive a 2.0 percentage point reduction to their market basket update for the fiscal year involved, after application of section 1888(e)(5)(B)(ii) of the Act (the MFP adjustment) and section 1888(e)(5)(B)(iii) of the Act (the 1 percent market basket increase for FY 2018). In addition, section 1888(e)(6)(A)(ii) of the Act states that application of the 2.0 percentage point reduction (after application of section 1888(e)(5)(B)(ii) and (iii) of the Act) may result in the market basket index percentage change being less than zero for a fiscal year, and may result in payment rates for a fiscal year being less than such payment rates for the preceding fiscal year. Section 1888(e)(6)(A)(iii) of the Act further specifies that the 2.0 percentage point reduction is applied in a noncumulative manner, so that any reduction made under section 1888(e)(6)(A)(i) of the Act applies only to the fiscal year involved, and that the reduction cannot be taken into account in computing the payment amount for a subsequent fiscal year.

6. Unadjusted Federal per Diem Rates for FY 2022

As discussed in the FY 2019 SNF PPS final rule (83 FR 39162), in FY 2020 we implemented a new case-mix classification system to classify SNF patients under the SNF PPS, the PDPM. As discussed in section V.B. of that final rule, under PDPM, the unadjusted Federal per diem rates are divided into six components, five of which are case-mix adjusted components (Physical Therapy (PT), Occupational Therapy (OT), Speech-Language Pathology (SLP), Nursing, and Non-Therapy Ancillaries (NTA)), and one of which is a non-case-mix component, as existed under the previous RUG–IV model. We propose to use the SNF market basket, adjusted as described previously, to adjust each per diem component of the Federal rates forward to reflect the change in the average prices for FY 2022 from the average prices for FY 2021. We propose to further adjust the rates by a wage index budget neutrality factor, described later in this section. Further, in the past, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS proposed and final rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

For FY 2022, we note an additional adjustment to the unadjusted per diem base rates. Specifically, section 134 in Division CC of the Consolidated Appropriations Act, 2021 included a provision amending section 1888(e)(2)(A)(iii) of the Act so as to add ''blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders . . . and items and services related to the furnishing of such factors under section 1842(o)(5)(C)'' to the list of items and services excludable from the Part A SNF PPS per diem payment, effective for items and services furnished on or after October 1, 2021. We discuss this provision further in section IV.B. of this proposed rule.

Section 1888(e)(4)(G)(iii) of the Act further requires that the Secretary ''provide for an appropriate proportional reduction in payments so that . . . the aggregate amount of such reductions is equal to the aggregate increase in payments attributable to the exclusion'' of the services from the Part A PPS per diem rates under section 1888(e)(2)(A)(iii) of the Act.

In the FY 2001 rulemaking cycle (65 FR 19202 and 46792), we established a methodology for computing such offsets in response to similar targeted consolidated billing exclusions added to section 1888(e)(2)(A)(iii) Act by section 103 of BBRA 1999. This methodology resulted in a reduction of 5 cents ($0.05) in the unadjusted urban and rural rates, using the identical data as used to establish the Part B add-on for a sample of approximately 1,500 SNFs from the 1995 base period. However, because this methodology relied on data from 1995, we propose a new methodology based on updated data (as discussed below) to apply the offsets required for the exclusion of the blood clotting factors and items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act (referred to collectively as the blood clotting factor exclusion), as specified under the

Consolidated Appropriations Act, 2021. We believe the use of the updated data will more accurately capture the actual cost of these factors, as using updated utilization data would reflect new types of blood clotting factors introduced in recent years and changes in utilization patterns of blood clotting factors since 1995.

The proposed methodology for calculating the blood clotting factor exclusion offset consists of five steps. In the first step, we begin with the total number of SNF utilization days for beneficiaries who have any amount of blood clotting factor (BCF) use in FY 2020. While we recognize the potential effects of the PHE for COVID–19 on SNF utilization during 2020, we believe we should use FY 2020 data because it is the most recent data available, and thus would best reflect the latest types of blood clotting factors and the most recent changes in utilization patterns; also, the FY 2020 data is the only data available that reflects utilization under the PDPM model rather than the RUG–IV model. However, in light of the potential impact of the PHE for COVID–19 on SNF utilization, particularly as it relates to those patients admitted with COVID–19 or whose stays utilized a PHE-related waiver (for example, the waiver which removes the requirement for a three-day prior inpatient hospital stay in order to receive SNF Part A coverage), we believe it would be appropriate to use a subset of the full FY 2020 SNF population which excludes patients diagnosed with COVID–19 and those stays which utilized a PHE-related waiver. We discuss this concept in more detail in relation to the recalibration of the PDPM parity adjustment, discussed in section V.C. of this proposed rule. As further explained below, we would note that using this subset population has very little impact on the result of the methodology described below. Throughout the discussion below, the term ''SNF beneficiary'' refers to beneficiaries in the FY 2020 subset population described above.

Since BCF use has historically been subject to SNF consolidated billing and its usage cannot be observed on billed SNF claims, this methodology resorts to claims from other settings to approximate BCF utilization in SNFs. Specifically, BCF use as well as items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act are identified by checking if any of the HCPCS codes listed in the Act, including J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211, are recorded on outpatient claims, which are claims submitted by institutional outpatient providers (such as a hospital outpatient department), or carrier claims, which are fee-for-service claims submitted by professional practitioners, such as physicians, physician assistants, clinical social workers, and nurse practitioners, and by some organizational providers, such as free-standing facilities. A SNF beneficiary with any BCF use is defined as a SNF beneficiary with at least one matched outpatient or carrier claim for blood clotting factors in FY 2020. To calculate the number of SNF utilization days for beneficiaries who have any amount of BCF use in FY 2020, we sum up the corresponding SNF utilization days of SNF beneficiaries with BCF use in FY 2020 (84 beneficiaries), which is 3,317 total utilization days.

In the second step, we estimate the BCF payment per day per SNF beneficiary with any BCF use in FY 2020, which would include payment for the BCFs and items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. There is no direct payment data to track BCF use in SNFs since BCF use is bundled within the Part A per diem payment. Therefore, we rely on payment in outpatient and carrier claims as a proxy for this step. Instead of calculating BCF payment per day for SNF beneficiaries in a SNF stay, we estimate the BCF payment per day for SNF beneficiaries outside of their SNF and inpatient stays, under the assumption that BCF payment per day for SNF beneficiaries is similar during and outside of SNF stays. Outpatient or carrier claims for BCF use that overlap with a SNF stay or an inpatient stay of a SNF beneficiary are excluded to ensure that BCF-related payment is fully captured in Part B claims instead of partially paid through Part A. Overlapping claims are identified when the outpatient claim ''From'' date or the carrier claim expense date fall within a SNF or inpatient stay's admission and discharge date window. The total BCF payment for SNF beneficiaries' BCF use observed through Part B claims in FY 2020 was $4,843,551. Next, to determine the corresponding utilizations days for SNF beneficiaries' BCF use, we need to carve out their utilization days in a SNF or inpatient setting for these target beneficiaries. We first determine the total SNF and inpatient utilization days for these beneficiaries in FY 2020, which totals 5,408. Next, we determine the total days that the beneficiaries with BCF use were not in a SNF or inpatient stay, which is 365 (for days in the year) multiplied by the number of SNF beneficiaries with BCF use (84), less the total SNF and inpatient utilization days for these beneficiaries (5,408), which is 20,142. Finally, we estimated the BCF payment per day, which is the total BCF payment observed in outpatient and carrier claims ($4,843,551) divided by the total days the beneficiaries were not in a SNF or inpatient (20,142). Thus, we calculate the BCF payment per day per SNF beneficiary to be $240.

In the third step, we calculate the percentage of SNF payment associated with BCF usage. We multiply the estimated BCF payment per day ($240 as determined in step 2) by the total SNF utilization days for SNF beneficiaries with BCF use in FY 2020 (3,317 as determined in step 1). This yields an estimated BCF payment for SNF beneficiaries in the study population of $797,640. Next, we divide this by the total SNF payment for the study population during FY 2020 ($22,636,345,868) to yield the percentage of SNF payment associated with BCF use, which we estimate to be 0.00352 percent.

In the fourth step, we calculate the urban and rural base rate reductions, by multiplying the proposed FY 2022 urban/rural base rates by the percentage of SNF payment associated with clotting factor use determined in step 3 (0.00352 percent). In the case of the proposed urban base rate of $434.79, this yields an urban base rate deduction of $0.02, which we would apply as a $0.01 reduction to the proposed FY 2022 NTA base rate and a $0.01 reduction to the proposed FY 2022 nursing base rate. In the case of the proposed rural base rate of $444.79, this yields a rural base rate deduction of $0.02, which we would apply as a $0.01 reduction to the proposed FY 2022 NTA base rates and a $0.01 reduction to the proposed FY 2022 nursing base rate. We would apply the reduction to the NTA and nursing base rates because BCF is a type of NTA and nursing resources are required to furnish this medication.

In step five, for purposes of impact analysis, we calculate the budget impact of the base rate reductions to be $782,785. We estimate the budget impact by multiplying the total FY2022 SNF baseline ($34,211,000,000) by the percentage of SNF payment for clotting factor (0.00352 percent). This results in a total reduction in SNF spending of $1.2 million. To compare the result of this proposed methodology to that which would have resulted from using the full FY 2020 SNF population, we note that if we had used the full FY 2020 SNF population, the resultant impact would be a reduction in SNF spending of $1.5 million, which represents 0.004551 percent of total

payments made under the SNF PPS. Given that these figures are so close as to result in the same two cent reduction in the FY 2022 SNF PPS unadjusted per diem rates, and given the reasons for using the subset population discussed in section V.C. of this proposed rule, we believe it is appropriate to use this subset population as the basis for the calculations described throughout this section.

We apply these rate reductions to the NTA and nursing components of the unadjusted Federal urban and rural per diem rate as shown in Tables 4 and 5.

Table 3 displays the methodology and figures used to calculate these rate reductions.

TABLE 3—ESTIMATION OF BLOOD CLOTTING FACTOR ON BASE RATE REDUCTION

Step 1: SNF Utilization Days of Benes with Any BCF Use:	
FY2020 # SNF Benes with Any BCF Use	84
FY2020 Total SNF Util Days for Benes with Any BCF Use	3,317
Step 2: Clotting Factor Payment per Day per SNF Bene with Any BCF Use:	
FY2020 Total Part B Clotting Factor Payment for Benes with Any BCF Use Outside of SNF or Inpatient Stay	$4,843,551
FY2020 Total SNF and Inpatient Util Days for Benes with Any BCF Use	5,408
FY2020 Total Days Not in SNF or Inpatient Stay for Benes with Any BCF Use	20,142
FY2020 Clotting Factor Payment per Day	$240
Step 3: % of SNF Payment Associated with Clotting Factor Use:	
FY2020 Estimated Clotting Factor Payment in SNF	$797,640
FY2020 Total SNF Payment	$22,636,345,868
% of SNF Payment Associated with Clotting Factor Use	0.00352%

Tables 4 and 5 reflect the updated unadjusted Federal rates for FY 2022, prior to adjustment for case-mix. The rates in Tables 4 and 5 include the reductions calculated in Table 3 for blood clotting factor use.

TABLE 4—FY 2022 UNADJUSTED FEDERAL RATE PER DIEM—URBAN

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$62.84	$58.49	$23.46	$109.55	$82.64	$98.10

TABLE 5—FY 2022 UNADJUSTED FEDERAL RATE PER DIEM—RURAL

Rate component	PT	OT	SLP	Nursing	NTA	Non-case-mix
Per Diem Amount	$71.63	$65.79	$29.56	$104.66	$78.96	$99.91

C. Case-Mix Adjustment

Under section 1888(e)(4)(G)(i) of the Act, the Federal rate also incorporates an adjustment to account for facility case-mix, using a classification system that accounts for the relative resource utilization of different patient types. The statute specifies that the adjustment is to reflect both a resident classification system that the Secretary establishes to account for the relative resource use of different patient types, as well as resident assessment data and other data that the Secretary considers appropriate. In the FY 2019 final rule (83 FR 39162, August 8, 2018), we finalized a new case-mix classification model, the PDPM, which took effect beginning October 1, 2019. The previous RUG–IV model classified most patients into a therapy payment group and primarily used the volume of therapy services provided to the patient as the basis for payment classification, thus creating an incentive for SNFs to furnish therapy regardless of the individual patient's unique characteristics, goals, or needs. PDPM eliminates this incentive and improves the overall accuracy and appropriateness of SNF payments by classifying patients into payment groups based on specific, data-driven patient characteristics, while simultaneously reducing the administrative burden on SNFs.

As we noted in the FY 2021 SNF PPS final rule (85 FR 47600), we continue to monitor the impact of PDPM implementation on patient outcomes and program outlays. We hope to release information in the future that relates to these issues, though we provide some of this information in section V.C. of this proposed rule. We also continue to monitor the impact of PDPM implementation as it relates to our intention to ensure that PDPM is implemented in a budget neutral manner, as discussed in the FY 2020 SNF PPS final rule (84 FR 38734). In section V.C. of this proposed rule, we discuss and solicit comments on a methodology to recalibrate the PDPM parity adjustment as appropriate to ensure budget neutrality, as we did after the implementation of RUG–IV in FY 2011.

The PDPM uses clinical data from the MDS to assign case-mix classifiers to each patient that are then used to calculate a per diem payment under the SNF PPS, consistent with the provisions of section 1888(e)(4)(G)(i) of the Act. As discussed in section IV.A. of this proposed rule, the clinical orientation of the case-mix classification system supports the SNF PPS's use of an administrative presumption that considers a beneficiary's initial case-mix classification to assist in making certain SNF level of care determinations. Further, because the MDS is used as a basis for payment, as well as a clinical assessment, we have provided extensive training on proper coding and the timeframes for MDS completion in our Resident Assessment Instrument (RAI) Manual. As we have stated in prior rules, for an MDS to be considered valid for use in determining payment, the MDS assessment should be completed in compliance with the instructions in the RAI Manual in effect at the time the assessment is completed. For payment and quality monitoring purposes, the RAI Manual consists of both the Manual

instructions and the interpretive guidance and policy clarifications posted on the appropriate MDS website at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/MDS30RAIManual.html.*

Under section 1888(e)(4)(H) of the Act, each update of the payment rates must include the case-mix classification methodology applicable for the upcoming FY. The proposed FY 2022 payment rates set forth in this proposed rule reflect the use of the PDPM case-mix classification system from October 1, 2021, through September 30, 2022. We list the proposed case-mix adjusted PDPM payment rates for FY 2022 separately for urban and rural SNFs, in Tables 6 and 7 with corresponding case-mix values.

Given the differences between the previous RUG–IV model and PDPM in terms of patient classification and billing, it was important that the format of Tables 6 and 7 reflect these differences. More specifically, under both RUG–IV and PDPM, providers use a Health Insurance Prospective Payment System (HIPPS) code on a claim to bill for covered SNF services. Under RUG–IV, the HIPPS code included the three-character RUG–IV group into which the patient classified as well as a two-character assessment indicator code that represented the assessment used to generate this code. Under PDPM, while providers still use a HIPPS code, the characters in that code represent different things. For example, the first character represents the PT and OT group into which the patient classifies. If the patient is classified into the PT and OT group ''TA'', then the first character in the patient's HIPPS code would be an A. Similarly, if the patient is classified into the SLP group ''SB'', then the second character in the patient's HIPPS code would be a B. The third character represents the Nursing group into which the patient classifies. The fourth character represents the NTA group into which the patient classifies. Finally, the fifth character represents the assessment used to generate the HIPPS code.

Tables 6 and 7 reflect the PDPM's structure. Accordingly, Column 1 of Tables 6 and 7 represents the character in the HIPPS code associated with a given PDPM component. Columns 2 and 3 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant PT group. Columns 4 and 5 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant OT group. Columns 6 and 7 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant SLP group. Column 8 provides the nursing case-mix group (CMG) that is connected with a given PDPM HIPPS character. For example, if the patient qualified for the nursing group CBC1, then the third character in the patient's HIPPS code would be a ''P.'' Columns 9 and 10 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant nursing group. Finally, columns 11 and 12 provide the case-mix index and associated case-mix adjusted component rate, respectively, for the relevant NTA group.

Tables 6 and 7 do not reflect adjustments which may be made to the SNF PPS rates as a result of the SNF VBP program, discussed in section III.D. of this proposed rule, or other adjustments, such as the variable per diem adjustment. Further, in the past, we used the revised OMB delineations adopted in the FY 2015 SNF PPS final rule (79 FR 45632, 45634), with updates as reflected in OMB Bulletin Nos, 15–01 and 17–01, to identify a facility's urban or rural status for the purpose of determining which set of rate tables would apply to the facility. As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) to identify a facility's urban or rural status effective beginning with FY 2021.

TABLE 6—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.53	$96.15	1.49	$87.15	0.68	$15.95	ES3	4.06	$444.77	3.24	$267.75
B	1.70	106.83	1.63	95.34	1.82	42.70	ES2	3.07	336.32	2.53	209.08
C	1.88	118.14	1.69	98.85	2.67	62.64	ES1	2.93	320.98	1.84	152.06
D	1.92	120.65	1.53	89.49	1.46	34.25	HDE2	2.40	262.92	1.33	109.91
E	1.42	89.23	1.41	82.47	2.34	54.90	HDE1	1.99	218.00	0.96	79.33
F	1.61	101.17	1.60	93.58	2.98	69.91	HBC2	2.24	245.39	0.72	59.50
G	1.67	104.94	1.64	95.92	2.04	47.86	HBC1	1.86	203.76	.....	.....
H	1.16	72.89	1.15	67.26	2.86	67.10	LDE2	2.08	227.86	.....	.....
I	1.13	71.01	1.18	69.02	3.53	82.81	LDE1	1.73	189.52	.....	.....
J	1.42	89.23	1.45	84.81	2.99	70.15	LBC2	1.72	188.43	.....	.....
K	1.52	95.52	1.54	90.07	3.7	86.80	LBC1	1.43	156.66	.....	.....
L	1.09	68.50	1.11	64.92	4.21	98.77	CDE2	1.87	204.86	.....	.....
M	1.27	79.81	1.30	76.04	.....	.....	CDE1	1.62	177.47	.....	.....
N	1.48	93.00	1.50	87.74	.....	.....	CBC2	1.55	169.80	.....	.....
O	1.55	97.40	1.55	90.66	.....	.....	CA2	1.09	119.41	.....	.....
P	1.08	67.87	1.09	63.75	.....	.....	CBC1	1.34	146.80	.....	.....
Q	.....	.....	.....	.....	.....	.....	CA1	0.94	102.98	.....	.....
R	.....	.....	.....	.....	.....	.....	BAB2	1.04	113.93	.....	.....
S	.....	.....	.....	.....	.....	.....	BAB1	0.99	108.45	.....	.....
T	.....	.....	.....	.....	.....	.....	PDE2	1.57	171.99	.....	.....
U	.....	.....	.....	.....	.....	.....	PDE1	1.47	161.04	.....	.....
V	.....	.....	.....	.....	.....	.....	PBC2	1.22	133.65	.....	.....
W	.....	.....	.....	.....	.....	.....	PA2	0.71	77.78	.....	.....
X	.....	.....	.....	.....	.....	.....	PBC1	1.13	123.79	.....	.....
Y	.....	.....	.....	.....	.....	.....	PA1	0.66	72.30	.....	.....

TABLE 7—PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL

PDPM Group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.53	$109.59	1.49	$98.03	0.68	$20.10	ES3	4.06	$424.92	3.24	$255.83
B	1.70	121.77	1.63	107.24	1.82	53.80	ES2	3.07	321.31	2.53	199.77
C	1.88	134.66	1.69	111.19	2.67	78.93	ES1	2.93	306.65	1.84	145.29
D	1.92	137.53	1.53	100.66	1.46	43.16	HDE2	2.40	251.18	1.33	105.02
E	1.42	101.71	1.41	92.76	2.34	69.17	HDE1	1.99	208.27	0.96	75.80
F	1.61	115.32	1.60	105.26	2.98	88.09	HBC2	2.24	234.44	0.72	56.85
G	1.67	119.62	1.64	107.90	2.04	60.30	HBC1	1.86	194.67	.....	.....
H	1.16	83.09	1.15	75.66	2.86	84.54	LDE2	2.08	217.69	.....	.....
I	1.13	80.94	1.18	77.63	3.53	104.35	LDE1	1.73	181.06	.....	.....
J	1.42	101.71	1.45	95.40	2.99	88.38	LBC2	1.72	180.02	.....	.....
K	1.52	108.88	1.54	101.32	3.7	109.37	LBC1	1.43	149.66	.....	.....
L	1.09	78.08	1.11	73.03	4.21	124.45	CDE2	1.87	195.71	.....	.....
M	1.27	90.97	1.30	85.53	.....	.....	CDE1	1.62	169.55	.....	.....
N	1.48	106.01	1.50	98.69	.....	.....	CBC2	1.55	162.22	.....	.....
O	1.55	111.03	1.55	101.97	.....	.....	CA2	1.09	114.08	.....	.....
P	1.08	77.36	1.09	71.71	.....	.....	CBC1	1.34	140.24	.....	.....
Q	.....	.....	.....	.....	.....	.....	CA1	0.94	98.38	.....	.....
R	.....	.....	.....	.....	.....	.....	BAB2	1.04	108.85	.....	.....
S	.....	.....	.....	.....	.....	.....	BAB1	0.99	103.61	.....	.....
T	.....	.....	.....	.....	.....	.....	PDE2	1.57	164.32	.....	.....
U	.....	.....	.....	.....	.....	.....	PDE1	1.47	153.85	.....	.....
V	.....	.....	.....	.....	.....	.....	PBC2	1.22	127.69	.....	.....
W	.....	.....	.....	.....	.....	.....	PA2	0.71	74.31	.....	.....
X	.....	.....	.....	.....	.....	.....	PBC1	1.13	118.27	.....	.....
Y	.....	.....	.....	.....	.....	.....	PA1	0.66	69.08	.....	.....

D. Wage Index Adjustment

Section 1888(e)(4)(G)(ii) of the Act requires that we adjust the Federal rates to account for differences in area wage levels, using a wage index that the Secretary determines appropriate. Since the inception of the SNF PPS, we have used hospital inpatient wage data in developing a wage index to be applied to SNFs. We propose to continue this practice for FY 2022, as we continue to believe that in the absence of SNF-specific wage data, using the hospital inpatient wage index data is appropriate and reasonable for the SNF PPS. As explained in the update notice for FY 2005 (69 FR 45786), the SNF PPS does not use the hospital area wage index's occupational mix adjustment, as this adjustment serves specifically to define the occupational categories more clearly in a hospital setting; moreover, the collection of the occupational wage data under the inpatient prospective payment system (IPPS) also excludes any wage data related to SNFs. Therefore, we believe that using the updated wage data exclusive of the occupational mix adjustment continues to be appropriate for SNF payments. As in previous years, we would continue to use the pre-reclassified IPPS hospital wage data, without applying the occupational mix, rural floor, or outmigration adjustment, as the basis for the SNF PPS wage index. For FY 2022, the updated wage data are for hospital cost reporting periods beginning on or after October 1, 2017 and before October 1, 2018 (FY 2018 cost report data).

We note that section 315 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted December 21, 2000) authorized us to establish a geographic reclassification procedure that is specific to SNFs, but only after collecting the data necessary to establish a SNF PPS wage index that is based on wage data from nursing homes. However, to date, this has proven to be unfeasible due to the volatility of existing SNF wage data and the significant amount of resources that would be required to improve the quality of the data. More specifically, auditing all SNF cost reports, similar to the process used to audit inpatient hospital cost reports for purposes of the IPPS wage index, would place a burden on providers in terms of recordkeeping and completion of the cost report worksheet. In addition, adopting such an approach would require a significant commitment of resources by CMS and the Medicare Administrative Contractors, potentially far in excess of those required under the IPPS given that there are nearly five times as many SNFs as there are inpatient hospitals. Therefore, while we continue to believe that the development of such an audit process could improve SNF cost reports in such a manner as to permit us to establish a SNF-specific wage index, we do not believe this undertaking is feasible at this time.

In addition, we propose to continue to use the same methodology discussed in the SNF PPS final rule for FY 2008 (72 FR 43423) to address those geographic areas in which there are no hospitals, and thus, no hospital wage index data on which to base the calculation of the FY 2022 SNF PPS wage index. For rural geographic areas that do not have hospitals and, therefore, lack hospital wage data on which to base an area wage adjustment, we propose to continue to use the average wage index from all contiguous Core-Based Statistical Areas (CBSAs) as a reasonable proxy. For FY 2022, there are no rural geographic areas that do not have hospitals, and thus, this methodology will not be applied. For rural Puerto Rico, we propose not to apply this methodology due to the distinct economic circumstances that exist there (for example, due to the close proximity to one another of almost all of Puerto Rico's various urban and non-urban areas, this methodology would produce a wage index for rural Puerto Rico that is higher than that in half of its urban areas); instead, we propose that we would continue to use the most recent wage index previously available for that area. For urban areas without specific hospital wage index data, we propose that we would use the average wage indexes of all of the urban areas within the state to serve as a reasonable proxy for the wage index of that urban

CBSA. For FY 2022, the only urban area without wage index data available is CBSA 25980, Hinesville-Fort Stewart, GA.

The wage index applicable to FY 2022 is set forth in Tables A and B available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

In the SNF PPS final rule for FY 2006 (70 FR 45026, August 4, 2005), we adopted the changes discussed in OMB Bulletin No. 03–04 (June 6, 2003), which announced revised definitions for MSAs and the creation of micropolitan statistical areas and combined statistical areas. In adopting the CBSA geographic designations, we provided for a 1-year transition in FY 2006 with a blended wage index for all providers. For FY 2006, the wage index for each provider consisted of a blend of 50 percent of the FY 2006 MSA-based wage index and 50 percent of the FY 2006 CBSA-based wage index (both using FY 2002 hospital data). We referred to the blended wage index as the FY 2006 SNF PPS transition wage index. As discussed in the SNF PPS final rule for FY 2006 (70 FR 45041), after the expiration of this 1-year transition on September 30, 2006, we used the full CBSA-based wage index values.

In the FY 2015 SNF PPS final rule (79 FR 45644 through 45646), we finalized changes to the SNF PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01, beginning in FY 2015, including a 1-year transition with a blended wage index for FY 2015. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010 **Federal Register** (75 FR 37246 through 37252). Subsequently, on July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided minor updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012 and July 1, 2013 and were adopted under the SNF PPS in the FY 2017 SNF PPS final rule (81 FR 51983, August 5, 2016). In addition, on August 15, 2017, OMB issued Bulletin No. 17–01 which announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300) which was adopted in the SNF PPS final rule for FY 2019 (83 FR 39173, August 8, 2018).

As discussed in the FY 2021 SNF PPS final rule (85 FR 47594), we adopted the revised OMB delineations identified in OMB Bulletin No. 18–04 (available at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5 percent cap on any decrease in a hospital's wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the SNF PPS.

As we previously stated in the FY 2008 SNF PPS proposed and final rules (72 FR 25538 through 25539, and 72 FR 43423), this and all subsequent SNF PPS rules and notices are considered to incorporate any updates and revisions set forth in the most recent OMB bulletin that applies to the hospital wage data used to determine the current SNF PPS wage index. We note that on March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the updates (available on the web at *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*). In the FY 2021 SNF PPS final rule (85 FR 47611), we stated that we intended to propose any updates from OMB Bulletin No. 20–01 in the FY 2022 SNF PPS proposed rule. After reviewing OMB Bulletin No. 20–01, we have determined that the changes in OMB Bulletin 20–01 encompassed delineation changes that do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, while we are proposing to adopt the updates set forth in OMB Bulletin No. 20–01 consistent with our longstanding policy of adopting OMB delineation updates, we note that specific wage index updates would not be necessary for FY 2022 as a result of adopting these OMB updates.

The proposed wage index applicable to FY 2022 is set forth in Tables A and B and is available on the CMS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html.*

Once calculated, we would apply the wage index adjustment to the labor-related portion of the Federal rate. Each year, we calculate a revised labor-related share, based on the relative importance of labor-related cost categories (that is, those cost categories that are labor-intensive and vary with the local labor market) in the input price index. In the SNF PPS final rule for FY 2018 (82 FR 36548 through 36566), we finalized a proposal to revise the labor-related share to reflect the relative importance of the 2014-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. Effective beginning FY 2022, as discussed in section V.A.4. of this proposed rule, for FY 2022, we are proposing to rebase and revise the labor-related share to reflect the relative importance of the proposed 2018-based SNF market basket cost weights for the following cost categories: Wages and Salaries; Employee Benefits; Professional fees: Labor-related; Administrative and Facilities Support services; Installation, Maintenance, and Repair services; All Other: Labor-Related Services; and a proportion of Capital-Related expenses. The proposed methodology for calculating the labor-related portion for FY 2022 is discussed in section V.A. of this proposed rule.

We calculate the labor-related relative importance from the SNF market basket, and it approximates the labor-related portion of the total costs after taking into account historical and projected price changes between the base year and FY 2022. The price proxies that move the different cost categories in the market basket do not necessarily change at the same rate, and the relative importance captures these changes. Accordingly, the relative importance figure more closely reflects the cost share weights for FY 2022 than the base year weights from the SNF market basket. We calculate the labor-related relative importance for FY 2022 in four steps. First, we compute the FY 2022 price index level for the total market basket and each cost category of the market basket. Second, we calculate a ratio for each cost category by dividing the FY 2022 price index level for that cost category by the total market basket price index level. Third, we determine

the FY 2022 relative importance for each cost category by multiplying this ratio by the base year (2018) weight. Finally, we add the FY 2022 relative importance for each of the labor-related cost categories (Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-related services; and a portion of Capital-Related expenses) to produce the FY 2022 labor-related relative importance. Table 8 summarizes the proposed labor-related share for FY 2022, based on IGI's fourth quarter 2020 forecast of the proposed 2018-based SNF market basket with historical data through third quarter 2020, compared to the labor-related share that was used for the FY 2021 SNF PPS final rule.

TABLE 8—LABOR-RELATED RELATIVE IMPORTANCE, FY 2021 AND FY 2022

	Relative importance, labor-related share, FY 2021 20:2 forecast [1]	Relative importance, labor-related share, FY 2022 20:4 forecast [2]
Wages and salaries	51.1	51.2
Employee benefits	9.9	9.5
Professional fees: Labor-related	3.7	3.5
Administrative & facilities support services	0.5	0.6
Installation, maintenance & repair services	0.6	0.4
All other: Labor-related services	2.6	1.9
Capital-related (.391)	2.9	3.0
Total	71.3	70.1

[1] Published in the **Federal Register** (85 FR 47605); based on the second quarter 2020 IHS Global Inc. forecast of the 2014-based SNF market basket, with historical data through first quarter 2020.
[2] Based on the fourth quarter 2020 IHS Global Inc. forecast of the proposed 2018-based SNF market basket.

To calculate the labor portion of the case-mix adjusted per diem rate, we would multiply the total case-mix adjusted per diem rate, which is the sum of all five case-mix adjusted components into which a patient classifies, and the non-case-mix component rate, by the FY 2022 labor-related share percentage provided in Table 8. The remaining portion of the rate would be the non-labor portion. Under the previous RUG–IV model, we included tables which provided the case-mix adjusted RUG–IV rates, by RUG–IV group, broken out by total rate, labor portion and non-labor portion, such as Table 9 of the FY 2019 SNF PPS final rule (83 FR 39175). However, as we discussed in the FY 2020 final rule (84 FR 38738), under PDPM, as the total rate is calculated as a combination of six different component rates, five of which are case-mix adjusted, and given the sheer volume of possible combinations of these five case-mix adjusted components, it is not feasible to provide tables similar to those that existed in the prior rulemaking.

Therefore, to aid stakeholders in understanding the effect of the wage index on the calculation of the SNF per diem rate, we have included a hypothetical rate calculation in Table 9.

Section 1888(e)(4)(G)(ii) of the Act also requires that we apply this wage index in a manner that does not result in aggregate payments under the SNF PPS that are greater or less than would otherwise be made if the wage adjustment had not been made. For FY 2022 (Federal rates effective October 1, 2021), we would apply an adjustment to fulfill the budget neutrality requirement. We would meet this requirement by multiplying each of the components of the unadjusted Federal rates by a budget neutrality factor, equal to the ratio of the weighted average wage adjustment factor for FY 2021 to the weighted average wage adjustment factor for FY 2022. For this calculation, we would use the same FY 2020 claims utilization data for both the numerator and denominator of this ratio. We define the wage adjustment factor used in this calculation as the labor portion of the rate component multiplied by the wage index plus the non-labor portion of the rate component. The proposed budget neutrality factor for FY 2022 would be 0.9999.

We note that if more recent data become available (for example, revised wage data), we would use such data, as appropriate, to determine the wage index budget neutrality factor in the SNF PPS final rule.

E. SNF Value-Based Purchasing Program

Beginning with payment for services furnished on October 1, 2018, section 1888(h) of the Act requires the Secretary to reduce the adjusted Federal per diem rate determined under section 1888(e)(4)(G) of the Act otherwise applicable to a SNF for services furnished during a fiscal year by 2 percent, and to adjust the resulting rate for a SNF by the value-based incentive payment amount earned by the SNF based on the SNF's performance score for that fiscal year under the SNF VBP Program. To implement these requirements, we finalized in the FY 2019 SNF PPS final rule the addition of § 413.337(f) to our regulations (83 FR 39178).

Please see section VII. of this proposed rule for a further discussion of our policies for the SNF VBP Program.

F. Adjusted Rate Computation Example

Tables 9, 10, and 11 provide examples generally illustrating payment calculations during FY 2022 under PDPM for a hypothetical 30-day SNF stay, involving the hypothetical SNF XYZ, located in Frederick, MD (Urban CBSA 23244), for a hypothetical patient who is classified into such groups that the patient's HIPPS code is NHNC1. Table 9 shows the adjustments made to the Federal per diem rates (prior to application of any adjustments under the SNF VBP program as discussed previously) to compute the provider's case-mix adjusted per diem rate for FY 2022, based on the patient's PDPM classification, as well as how the variable per diem (VPD) adjustment factor affects calculation of the per diem rate for a given day of the stay. Table 10 shows the adjustments made to the case-mix adjusted per diem rate from Table 9 to account for the provider's wage index. The wage index used in this example is based on the FY 2022 SNF PPS wage index that appears in Table A available on the CMS website at *http://*

www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/WageIndex.html. Finally, Table 11 provides the case-mix and wage index adjusted per-diem rate for this patient for each day of the 30-day stay, as well as the total payment for this stay. Table 11 also includes the VPD adjustment factors for each day of the patient's stay, to clarify why the patient's per diem rate changes for certain days of the stay. As illustrated in Table 9, SNF XYZ's total PPS payment for this particular patient's stay would equal $20,571.17.

TABLE 9—PDPM CASE-MIX ADJUSTED RATE COMPUTATION EXAMPLE

Per Diem Rate Calculation				
Component	Component group	Component rate	VPD adjustment factor	VPD adj. rate
PT	N	$93.00	1.00	$93.00
OT	N	87.74	1.00	87.74
SLP	H	67.10	1.00	67.10
Nursing	N	169.80	1.00	169.80
NTA	C	152.06	3.00	456.18
Non-Case-Mix		98.10		98.10
Total PDPM Case-Mix Adj. Per Diem				$971.92

TABLE 10—WAGE INDEX ADJUSTED RATE COMPUTATION EXAMPLE

PDPM wage index adjustment calculation						
HIPPS code	PDPM case-mix adjusted per diem	Labor portion	Wage index	Wage index adjusted rate	Non-labor portion	Total case mix and wage index adj. rate
NHNC1	$971.92	$681.32	0.9776	$666.06	$290.60	$956.66

TABLE 11—ADJUSTED RATE COMPUTATION EXAMPLE

Day of stay	NTA VPD adjustment factor	PT/OT VPD adjustment factor	Case mix and wage index adjusted per diem rate
1	3.0	1.0	$956.66
2	3.0	1.0	956.66
3	3.0	1.0	956.66
4	1.0	1.0	657.31
5	1.0	1.0	657.31
6	1.0	1.0	657.31
7	1.0	1.0	657.31
8	1.0	1.0	657.31
9	1.0	1.0	657.31
10	1.0	1.0	657.31
11	1.0	1.0	657.31
12	1.0	1.0	657.31
13	1.0	1.0	657.31
14	1.0	1.0	657.31
15	1.0	1.0	657.31
16	1.0	1.0	657.31
17	1.0	1.0	657.31
18	1.0	1.0	657.31
19	1.0	1.0	657.31
20	1.0	1.0	657.31
21	1.0	0.98	653.76
22	1.0	0.98	653.76
23	1.0	0.98	653.76
24	1.0	0.98	653.76
25	1.0	0.98	653.76
26	1.0	0.98	653.76
27	1.0	0.98	653.76
28	1.0	0.96	650.20
29	1.0	0.96	650.20
30	1.0	0.96	650.20
Total Payment			20,571.17

IV. Additional Aspects of the SNF PPS

A. SNF Level of Care—Administrative Presumption

The establishment of the SNF PPS did not change Medicare's fundamental requirements for SNF coverage. However, because the case-mix classification is based, in part, on the beneficiary's need for skilled nursing care and therapy, we have attempted, where possible, to coordinate claims review procedures with the existing resident assessment process and case-mix classification system discussed in section III.B.3. of this proposed rule. This approach includes an administrative presumption that utilizes a beneficiary's correct assignment, at the outset of the SNF stay, of one of the case-mix classifiers designated for this purpose to assist in making certain SNF level of care determinations.

In accordance with § 413.345, we include in each update of the Federal payment rates in the **Federal Register** a discussion of the resident classification system that provides the basis for case-mix adjustment. We also designate those specific classifiers under the case-mix classification system that represent the required SNF level of care, as provided in 42 CFR 409.30. This designation reflects an administrative presumption that those beneficiaries who are correctly assigned one of the designated case-mix classifiers on the initial Medicare assessment are automatically classified as meeting the SNF level of care definition up to and including the assessment reference date (ARD) for that assessment.

A beneficiary who does not qualify for the presumption is not automatically classified as either meeting or not meeting the level of care definition, but instead receives an individual determination on this point using the existing administrative criteria. This presumption recognizes the strong likelihood that those beneficiaries who are correctly assigned one of the designated case-mix classifiers during the immediate post-hospital period would require a covered level of care, which would be less likely for other beneficiaries.

In the July 30, 1999 final rule (64 FR 41670), we indicated that we would announce any changes to the guidelines for Medicare level of care determinations related to modifications in the case-mix classification structure. The FY 2018 final rule (82 FR 36544) further specified that we would henceforth disseminate the standard description of the administrative presumption's designated groups via the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html* (where such designations appear in the paragraph entitled ''Case Mix Adjustment''), and would publish such designations in rulemaking only to the extent that we actually intend to propose changes in them. Under that approach, the set of case-mix classifiers designated for this purpose under PDPM was finalized in the FY 2019 SNF PPS final rule (83 FR 39253) and is posted on the SNF PPS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html*), in the paragraph entitled ''Case Mix Adjustment.''

However, we note that this administrative presumption policy does not supersede the SNF's responsibility to ensure that its decisions relating to level of care are appropriate and timely, including a review to confirm that any services prompting the assignment of one of the designated case-mix classifiers (which, in turn, serves to trigger the administrative presumption) are themselves medically necessary. As we explained in the FY 2000 SNF PPS final rule (64 FR 41667), the administrative presumption is itself rebuttable in those individual cases in which the services actually received by the resident do not meet the basic statutory criterion of being reasonable and necessary to diagnose or treat a beneficiary's condition (according to section 1862(a)(1) of the Act). Accordingly, the presumption would not apply, for example, in those situations where the sole classifier that triggers the presumption is itself assigned through the receipt of services that are subsequently determined to be not reasonable and necessary. Moreover, we want to stress the importance of careful monitoring for changes in each patient's condition to determine the continuing need for Part A SNF benefits after the ARD of the initial Medicare assessment.

B. Consolidated Billing

Sections 1842(b)(6)(E) and 1862(a)(18) of the Act (as added by section 4432(b) of the BBA 1997) require a SNF to submit consolidated Medicare bills to its Medicare Administrative Contractor (MAC) for almost all of the services that its residents receive during the course of a covered Part A stay. In addition, section 1862(a)(18) of the Act places the responsibility with the SNF for billing Medicare for physical therapy, occupational therapy, and speech-language pathology services that the resident receives during a noncovered stay. Section 1888(e)(2)(A) of the Act excludes a small list of services from the consolidated billing provision (primarily those services furnished by physicians and certain other types of practitioners), which remain separately billable under Part B when furnished to a SNF's Part A resident. These excluded service categories are discussed in greater detail in section V.B.2. of the May 12, 1998 interim final rule (63 FR 26295 through 26297).

A detailed discussion of the legislative history of the consolidated billing provision is available on the SNF PPS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/Downloads/Legislative_History_2018-10-01.pdf.* In particular, section 103 of the BBRA 1999 amended section 1888(e)(2)(A)(iii) of the Act by further excluding a number of individual high-cost, low probability services, identified by Healthcare Common Procedure Coding System (HCPCS) codes, within several broader categories (chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices) that otherwise remained subject to the provision. We discuss this BBRA 1999 amendment in greater detail in the SNF PPS proposed and final rules for FY 2001 (65 FR 19231 through 19232, April 10, 2000, and 65 FR 46790 through 46795, July 31, 2000), as well as in Program Memorandum AB–00–18 (Change Request #1070), issued March 2000, which is available online at *www.cms.gov/transmittals/downloads/ab001860.pdf.*

As explained in the FY 2001 proposed rule (65 FR 19232), the amendments enacted in section 103 of the BBRA 1999 not only identified for exclusion from this provision a number of particular service codes within four specified categories (that is, chemotherapy items, chemotherapy administration services, radioisotope services, and customized prosthetic devices), but also gave the Secretary the authority to designate additional, individual services for exclusion within each of these four specified service categories. In the proposed rule for FY 2001, we also noted that the BBRA 1999 Conference report (H.R. Rep. No. 106–479 at 854 (1999) (Conf. Rep.)) characterizes the individual services that this legislation targets for exclusion as high-cost, low probability events that could have devastating financial impacts because their costs far exceed the payment SNFs receive under the PPS. According to the conferees, section 103(a) of the BBRA 1999 is an attempt to exclude from the PPS certain services and costly items that are provided infrequently in SNFs. By contrast, the amendments enacted in section 103 of

the BBRA 1999 do not designate for exclusion any of the remaining services within those four categories (thus, leaving all of those services subject to SNF consolidated billing), because they are relatively inexpensive and are furnished routinely in SNFs.

As we further explained in the final rule for FY 2001 (65 FR 46790), and as is consistent with our longstanding policy, any additional service codes that we might designate for exclusion under our discretionary authority must meet the same statutory criteria used in identifying the original codes excluded from consolidated billing under section 103(a) of the BBRA 1999: They must fall within one of the four service categories specified in the BBRA 1999; and they also must meet the same standards of high cost and low probability in the SNF setting, as discussed in the BBRA 1999 Conference report. Accordingly, we characterized this statutory authority to identify additional service codes for exclusion as essentially affording the flexibility to revise the list of excluded codes in response to changes of major significance that may occur over time (for example, the development of new medical technologies or other advances in the state of medical practice) (65 FR 46791).

Effective with items and services furnished on or after October 1, 2021, section 134 in Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) has established an additional category of excluded codes in section 1888(e)(2)(A)(iii)(VI) of the Act, for certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders along with items and services related to the furnishing of such factors under section 1842(o)(5)(C) of the Act. The specific factors, and items and services related to the furnishing of such factors, excluded under this provision are those identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211. Like the provisions enacted in the BBRA 1999, new section 1888(e)(2)(A)(iii)(VI) of the Act gives the Secretary the authority to designate additional items and services for exclusion within the category of items and services described in that section. Section 1888(e)(4)(G)(iii) of the Act further requires that for any services that are unbundled from consolidated billing under section 1888(e)(2)(A)(iii) of the Act (and, thus, become qualified for separate payment under Part B), there must also be a corresponding proportional reduction made in aggregate SNF payments under Part A. Accordingly, using the methodology described in section III.B.6. of this proposed rule, we propose to make a proportional reduction of $0.02 in the unadjusted urban and rural rates to reflect these new exclusions, effective for items and services furnished on or after October 1, 2021.

In this proposed rule, we specifically invite public comments identifying HCPCS codes in any of these five service categories (chemotherapy items, chemotherapy administration services, radioisotope services, customized prosthetic devices, and blood clotting factors) representing recent medical advances that might meet our criteria for exclusion from SNF consolidated billing. We may consider excluding a particular service if it meets our criteria for exclusion as specified previously. We request that commenters identify in their comments the specific HCPCS code that is associated with the service in question, as well as their rationale for requesting that the identified HCPCS code(s) be excluded.

We note that the original BBRA amendment and the Consolidated Appropriations Act, 2021 identified a set of excluded items and services by means of specifying individual HCPCS codes within the designated categories that were in effect as of a particular date (in the case of the BBRA 1999, July 1, 1999, and in the case of the Consolidated Appropriations Act, 2021, July 1, 2020), as subsequently modified by the Secretary. In addition, as noted above, the statute (section 1888(e)(2)(A)(iii)(II)–(VI) of the Act) gives the Secretary authority to identify additional items and services for exclusion within the categories of items and services described in the statute, which are also designated by HCPCS code. Designating the excluded services in this manner makes it possible for us to utilize program issuances as the vehicle for accomplishing routine updates to the excluded codes to reflect any minor revisions that might subsequently occur in the coding system itself (such as the assignment of a different code number to a service already designated as excluded, or the creation of a new code for a type of service that falls within one of the established exclusion categories and meets our criteria for exclusion (for example, J7212, ''factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram'', which became effective on January 1, 2021 and would fall in the blood clotting factor exclusion category).

Accordingly, in the event that we identify through the current rulemaking cycle any new services that would actually represent a substantive change in the scope of the exclusions from SNF consolidated billing, we would identify these additional excluded services by means of the HCPCS codes that are in effect as of a specific date (in this case, October 1, 2021). By making any new exclusions in this manner, we could similarly accomplish routine future updates of these additional codes through the issuance of program instructions. The latest list of excluded codes can be found on the SNF Consolidated Billing website at *https://www.cms.gov/Medicare/Billing/SNFConsolidatedBilling.*

C. Payment for SNF-Level Swing-Bed Services

Section 1883 of the Act permits certain small, rural hospitals to enter into a Medicare swing-bed agreement, under which the hospital can use its beds to provide either acute- or SNF-level care, as needed. For critical access hospitals (CAHs), Part A pays on a reasonable cost basis for SNF-level services furnished under a swing-bed agreement. However, in accordance with section 1888(e)(7) of the Act, SNF-level services furnished by non-CAH rural hospitals are paid under the SNF PPS, effective with cost reporting periods beginning on or after July 1, 2002. As explained in the FY 2002 final rule (66 FR 39562), this effective date is consistent with the statutory provision to integrate swing-bed rural hospitals into the SNF PPS by the end of the transition period, June 30, 2002.

Accordingly, all non-CAH swing-bed rural hospitals have now come under the SNF PPS. Therefore, all rates and wage indexes outlined in earlier sections of this proposed rule for the SNF PPS also apply to all non-CAH swing-bed rural hospitals. As finalized in the FY 2010 SNF PPS final rule (74 FR 40356 through 40357), effective October 1, 2010, non-CAH swing-bed rural hospitals are required to complete an MDS 3.0 swing-bed assessment which is limited to the required demographic, payment, and quality items. As discussed in the FY 2019 SNF PPS final rule (83 FR 39235), revisions were made to the swing bed assessment to support implementation of PDPM, effective October 1, 2019. A discussion of the assessment schedule and the MDS effective beginning FY 2020 appears in the FY 2019 SNF PPS final rule (83 FR 39229 through 39237). The latest changes in the MDS for swing-bed rural hospitals appear on the SNF PPS website at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/index.html.*

D. Revisions to the Regulation Text

We propose to make certain revisions in the regulation text itself. Specifically, we propose to redesignate current 42 CFR 411.15(p)(2)(xvii) and 489.20(s)(17) to § 411.15(p)(2)(xviii) and 489.20(s)(18), and update the regulation text at §§ 411.15(p)(2)(xvii) and 489.20(s)(17) to reflect the recently-enacted exclusion from SNF consolidated billing at section 1888(e)(2)(A)(iii)(VI) of the Act effective for items and services furnished on or after October 1, 2021. Specifically, proposed revised §§ 411.15(p)(2)(xvii) and 489.20(s)(17) would reflect the exclusion of certain blood clotting factors for the treatment of patients with hemophilia and other bleeding disorders (identified by designated HCPCS codes in effect as of July 1, 2020, as subsequently modified by CMS), and items and services related to the furnishing of such factors, and would allow for the exclusion of any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors. In addition, we are proposing to make conforming changes to the regulation text at §§ 411.15(p)(2)(xiii) through (xvi) and 489.20(s)(13) through (16) to reflect the authority that has always existed for CMS to make updates to the list of excluded codes as provided in section 1888(e)(2)(A)(iii)(II) through (V) of the Act, and as discussed in section IV. C. of this proposed rule.

V. Other SNF PPS Issues

A. Rebasing and Revising the SNF Market Basket

Section 1888(e)(5)(A) of the Act requires the Secretary to establish a market basket index that reflects the changes over time in the prices of an appropriate mix of goods and services included in covered SNF services. Accordingly, we have developed a SNF market basket index that encompasses the most commonly used cost categories for SNF routine services, ancillary services, and capital-related expenses. We use the SNF market basket index, adjusted in the manner described in section III.B. of this proposed rule, to update the SNF PPS per diem rates and to determine the labor-related share on an annual basis.

The SNF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (the proposed base period is 2018) and total base period expenditures are estimated for a set of mutually exclusive and exhaustive spending categories and the proportion of total costs that each category represents is calculated. These proportions are called cost or expenditure weights. Second, each expenditure category is matched to an appropriate price or wage variable, referred to as a price proxy. In nearly every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the expenditure weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the expenditure weights multiplied by their price levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

Effective for cost reporting periods beginning on or after July 1, 1998, we revised and rebased our 1977 routine costs input price index and adopted a total expenses SNF input price index using FY 1992 as the base year. In the FY 2002 SNF PPS final rule (66 FR 39582), we rebased and revised the market basket to a base year of FY 1997. In the FY 2008 SNF PPS final rule (72 FR 43425), we rebased and revised the market basket to a base year of FY 2004. In the FY 2014 SNF PPS final rule (78 FR 47939), we revised and rebased the SNF market basket, which included updating the base year from FY 2004 to FY 2010. Lastly, in the FY 2018 SNF PPS final rule (82 FR 36548), we revised and rebased the SNF market basket, which included updating the base year from FY 2010 to FY 2014. For FY 2022 and subsequent fiscal years, we are proposing to rebase the market basket to reflect 2018 Medicare-allowable total cost data (routine, ancillary, and capital-related) from freestanding SNFs and to revise applicable cost categories and price proxies used to determine the market basket. Medicare-allowable costs are those costs that are eligible to be paid under the SNF PPS. For example, the SNF market basket excludes home health agency (HHA) costs as these costs would be paid under the HHA PPS and, therefore, these costs are not SNF PPS Medicare-allowable costs. We propose to maintain our policy of using data from freestanding SNFs, which represent 93 percent of the total SNFs shown in Table 12. We believe using freestanding Medicare cost report (MCR) data, as opposed to the hospital-based SNF MCR data, for the proposed cost weight calculation is most appropriate because of the complexity of hospital-based data and the representativeness of the freestanding data. Because hospital-based SNF expenses are embedded in the hospital cost report, any attempt to incorporate data from hospital-based facilities requires more complex calculations and assumptions regarding the ancillary costs related to the hospital-based SNF unit. We believe the use of freestanding SNF cost report data is technically appropriate for reflecting the cost structures of SNFs serving Medicare beneficiaries.

We are proposing to use 2018 as the base year as we believe that the 2018 MCRs represent the most recent, complete set of MCR data available to develop cost weights for SNFs at the time of rulemaking. We believe it is important to regularly rebase and revise the SNF market to reflect more recent data. Historically, the cost weights change minimally from year to year as they represent percent of total costs rather than cost levels; however, given the PHE for COVID–19, we will continue to monitor the upcoming MCR data to see if a more frequent rebasing schedule is necessary than our recent historical precedent of about every 4 years. The 2018 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2017 and before October 1, 2018. While these dates appear to reflect fiscal year data, we note that a Medicare cost report that begins in this timeframe is generally classified as a ''2018 cost report''. For example, we found that of the available 2018 Medicare cost reports for SNFs, approximately 7 percent had an October 1, 2017 begin date, approximately 70 percent of the reports had a January 1, 2018 begin date, and approximately 12 percent had a July 1, 2018 begin date. For this reason, we are defining the base year of the market basket as ''2018-based'' instead of ''FY 2018-based''.

Specifically, we are proposing to develop cost category weights for the 2018-based SNF market basket in two stages. First, we are proposing to derive eight major expenditures or cost weights from the 2018 MCR data (CMS Form 2540–10, OMB NO. 0938–0463) for freestanding SNFs: Wages and Salaries; Employee Benefits; Contract Labor; Pharmaceuticals; Professional Liability

Insurance; Home Office/Related Organization Contract Labor; Capital-related; and a residual ''All Other''. These are the same cost categories calculated using the 2014 MCR data for the 2014-based SNF market basket. The residual ''All Other'' category would reflect all remaining costs that are not captured in the other seven cost categories. Second, we are proposing to divide the residual ''All Other'' cost category into more detailed subcategories, using U.S. Department of Commerce Bureau of Economic Analysis' (BEA) 2012 Benchmark Input-Output (I–O) ''use table before redefinitions, purchaser's value'' for the Nursing and Community Care Facilities industry (NAICS 623A00) aged to 2018 using applicable price proxy growth for each category of costs. Furthermore, we are proposing to continue to use the same overall methodology as was used for the 2014-based SNF market basket to develop the capital related cost weights of the proposed 2018-based SNF market basket.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data To Develop Major Cost Weights

In order to create a market basket that is representative of freestanding SNF providers serving Medicare patients and to help ensure accurate major cost weights (which is the percent of total Medicare-allowable costs, as defined below), we propose to apply edits to remove reporting errors and outliers. Specifically, the SNF MCRs used to calculate the market basket cost weights exclude any providers that reported costs less than or equal to zero for the following categories: Total facility costs (Worksheet B, part 1, column 18, line 100); total operating costs (Worksheet B, part 1, column 18, line 100 less Worksheet B, part 2, column 18, line 100); Medicare general inpatient routine service costs (Worksheet D, part 1, column 1, line 1); and Medicare PPS payments (Worksheet E, part 3, column 1, line 1). We also limited our sample to providers that had a MCR reporting period that was between 10 and 14 months. The final sample used included roughly 13,500 MCRs (about 90 percent of the universe of SNF MCRs for 2018). The sample of providers is representative of the national universe of providers by region, by ownership-type (proprietary, nonprofit, and government), and by urban/rural status.

Additionally, for all of the major cost weights, except Home Office/Related Organization Contract Labor costs, the data are trimmed to remove outliers (a standard statistical process) by: (1) Requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable costs are greater than zero; and (2) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable costs). We note that missing values are assumed to be zero, consistent with the methodology for how missing values are treated in the 2014-based market basket methodology.

For the Home Office/Related Organization Contract Labor cost weight, we propose to first exclude providers whose Home Office/Related Organization Contract Labor costs are greater than Medicare-allowable total costs and then apply a trim that excludes those reporters with a Home Office/Related Organization Contract Labor cost weight above the 99th percentile. This allows providers with no Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation . If we were to trim the top and bottom Home Office/Related Organization Contract Labor cost weight, we would exclude providers with a zero cost weight and the MCR data (Worksheet S–2 line 45) indicate that not all SNF providers have a home office. Providers without a home office would report administrative costs that might typically be associated with a home office in the Wages and Salaries and Employee Benefits cost weights, or in the residual ''All-Other'' cost weight if they purchased these types of services from external contractors. We believe the trimming methodology that excludes those who report Home Office costs above the 99th percentile is appropriate as it removes extreme outliers while also allowing providers with zero Home Office/Related Organization Contract Labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation.

The trimming process is done individually for each cost category so that providers excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these proposed trimming methods are the same types of edits performed for the 2014-based SNF market basket, as well as other PPS market baskets (including but not limited to the IPPS market basket and HHA market basket). We believe this trimming process improves the accuracy of the data used to compute the major cost weights by removing possible data misreporting.

The final weights of the proposed 2018-based SNF market basket are based on weighted means. For example, the aggregate Wages and Salaries cost weight, after trimming, is equal to the sum of total Medicare-allowable wages and salaries of all providers divided by the sum of total Medicare-allowable costs for all providers in the sample. This methodology is consistent with the methodology used to calculate the 2014-based SNF market basket cost weights and other PPS market basket cost weights. We note that for each of the cost weights, we evaluated the distribution of providers and costs by region, by ownership-type, and by urban/rural status. For all of the cost weights, with the exception of the PLI (which is discussed in more detail later), the trimmed sample was nationally representative.

For all of the cost weights, we use Medicare-allowable total costs as the denominator (for example, Wages and Salaries cost weight = Wages and Salaries costs divided by Medicare-allowable total costs). Medicare-allowable total costs were equal to total costs (after overhead allocation) from Worksheet B part I, column 18, for lines 30, 40 through 49, 51, 52, and 71 plus estimated Medicaid drug costs, as defined below. We included estimated Medicaid drug costs in the pharmacy cost weight, as well as the denominator for total Medicare-allowable costs. This is the same methodology used for the 2014-based SNF market basket. The inclusion of Medicaid drug costs was finalized in the FY 2008 SNF PPS final rule (72 FR 43425 through 43430), and for the same reasons set forth in that final rule, we are proposing to continue to use this methodology in the proposed 2018-based SNF market basket.

We describe the detailed methodology for obtaining costs for each of the eight cost categories determined from the Medicare Cost Report below. The methodology used in the 2014-based SNF market basket can be found in the FY 2018 SNF PPS final rule (82 FR 36548 through 36555).

(1) *Wages and Salaries:* To derive Wages and Salaries costs for the Medicare-allowable cost centers, we are proposing first to calculate total facility wages and salaries costs as reported on Worksheet S–3, part II, column 3, line 1. We are then proposing to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas), as well as a portion of overhead wages and salaries attributable to these excluded areas. Excluded area wages and salaries are equal to wages and salaries as reported on Worksheet S–3, part II, column 3, lines 3, 4, and 7

through 11 plus nursing facility and non-reimbursable salaries from Worksheet A, column 1, lines 31, 32, 50, and 60 through 63.

Overhead wages and salaries are attributable to the entire SNF facility; therefore, we are proposing to include only the proportion attributable to the Medicare-allowable cost centers. We are proposing to estimate the proportion of overhead wages and salaries attributable to the non-Medicare-allowable costs centers in two steps. First, we propose to estimate the ratio of excluded area wages and salaries (as defined above) to non-overhead total facility wages and salaries (total facility wages and salaries (Worksheet S–3, part II, column 3, line 1) less total overhead wages and salaries (Worksheet S–3, Part III, column 3, line 14)). Next, we propose to multiply total overhead wages and salaries by the ratio computed in step 1. We excluded providers whose excluded areas wages and salaries were greater than total facility wages and salaries and/or their excluded area overhead wages and salaries were greater than total facility wages and salaries (about 50 providers). This is similar to the methodology used to derive Wages and Salaries costs in the 2014-based SNF market basket. For the 2014-based SNF market basket, we estimated the proportion of overhead wages and salaries that is attributable to the non-Medicare allowable costs centers (that is, excluded areas) by multiplying the ratio of excluded area wages and salaries (as defined above) to total wages and salaries as reported on Worksheet S–3, Part II, column 3, line 1 by total overhead wages and salaries as reported on Worksheet S–3, Part III, column 3, line 14.

(2) *Employee Benefits:* Medicare-allowable employee benefits are equal to total facility benefits as reported on Worksheet S–3, part II, column 3, lines 17 through 19 minus non-Medicare-allowable (that is, excluded area) employee benefits and minus a portion of overhead benefits attributable to these excluded areas. Excluded area employee benefits are derived by multiplying total excluded area wages and salaries (as defined above in the 'Wages and Salaries' section) times the ratio of total facility benefits to total facility wages and salaries. This ratio of benefits to wages and salaries is defined as total facility benefit costs to total facility wages and salary costs (as reported on Worksheet S–3, part II, column 3, line 1). Likewise, the portion of overhead benefits attributable to the excluded areas is derived by multiplying overhead wages and salaries attributable to the excluded areas (as defined in the 'Wages and Salaries' section) times the ratio of total facility benefit costs to total facility wages and salary costs (as defined above). Similar to the Wages and Salaries cost weight, we excluded providers whose excluded areas benefits were greater than total facility benefits and/or their excluded area overhead benefits were greater than total facility benefits (zero providers were excluded because of this edit). This is similar to the methodology used to derive Employee Benefits costs in the 2014-based SNF market basket.

(3) *Contract Labor:* We are proposing to derive Medicare-allowable contract labor costs from Worksheet S–3, part II, column 3, line 14, which reflects costs for contracted direct patient care services (that is, nursing, therapeutic, rehabilitative, or diagnostic services furnished under contract rather than by employees and management contract services). This is the same methodology used to derive the Contract Labor costs in the 2014-based SNF market basket.

(4) *Pharmaceuticals:* We are proposing to calculate pharmaceuticals costs using the non-salary costs from the Pharmacy cost center (Worksheet B, part I, column 0, line 11 less Worksheet A, column 1, line 11) and the Drugs Charged to Patients' cost center (Worksheet B, part I, column 0, line 49 less Worksheet A, column 1, line 49). Since these drug costs were attributable to the entire SNF and not limited to Medicare-allowable services, we propose to adjust the drug costs by the ratio of Medicare-allowable pharmacy total costs (Worksheet B, part I, column 11, for lines 30, 40 through 49, 51, 52, and 71) to total pharmacy costs from Worksheet B, part I, column 11, line 11. Worksheet B, part I allocates the general service cost centers, which are often referred to as ''overhead costs'' (in which pharmacy costs are included) to the Medicare-allowable and non-Medicare-allowable cost centers. This adjustment was made for those providers who reported Pharmacy cost center expenses. Otherwise, we assumed the non-salary Drugs Charged to Patients costs were Medicare-allowable. Since drug costs for Medicare patients are included in the SNF PPS per diem rate, a provider with Medicare days should have also reported costs in the Drugs Charged to Patient cost center. We found a small number of providers (roughly 60) did not report Drugs Charged to Patients' costs despite reporting Medicare days (an average of about 2,600 Medicare days per provider) and, therefore, these providers were excluded from the Pharmaceuticals cost weight calculations. This is similar to the methodology used for the 2014-based SNF market basket.

Second, as was done for the 2014-based SNF market basket, we propose to continue to adjust the drug expenses reported on the MCR to include an estimate of total Medicaid drug costs, which are not represented in the Medicare-allowable drug cost weight. As stated previously in this section, the proposed 2018-based SNF market basket reflects total Medicare-allowable costs (that is, total costs for all payers for those services reimbursable under the SNF PPS). For the FY 2006-based SNF market basket (72 FR 43426), commenters noted that the total pharmaceutical costs reported on the MCR did not include pharmaceutical costs for dual-eligible Medicaid patients as these were directly reimbursed by Medicaid. Since all of the other cost category weights reflect expenses associated with treating Medicaid patients (including the compensation costs for dispensing these drugs), we made an adjustment to include these Medicaid drug expenses so the market basket cost weights would be calculated consistently.

Similar to the 2014-based SNF market basket, we propose to estimate Medicaid drug costs based on data representing dual-eligible Medicaid beneficiaries. Medicaid drug costs are estimated by multiplying Medicaid dual-eligible drug costs per day times the number of Medicaid days as reported in the Medicare-allowable skilled nursing cost center (Worksheet S–3, part I, column 5, line 1) in the SNF MCR. Medicaid dual-eligible drug costs per day (where the day represents an unduplicated drug supply day) were estimated using 2018 Part D claims for those dual-eligible beneficiaries who had a Medicare SNF stay during the year. The total drug costs per unduplicated day for 2018 of $24.48 represented all drug costs (including the drug ingredient cost, the dispensing fee, vaccine administration fee and sales tax) incurred during the 2018 calendar year for those dual-eligible beneficiaries who had a SNF Medicare stay during that 2018 calendar year. Therefore, they include drug costs incurred during a Medicaid SNF stay occurring in the 2018 calendar year. By comparison, the 2014-based SNF market basket also relied on data from the Part D claims, which yielded a dual-eligible Medicaid drug cost per day of $19.62 for 2014.

We continue to believe that Medicaid dual-eligible beneficiaries are a reasonable proxy for the estimated drug costs per day incurred by Medicaid patients staying in a skilled nursing unit under a Medicaid stay. The skilled nursing unit is the Medicare-allowable unit in a SNF, which encompasses more

skilled nursing and rehabilitative care compared to a nursing facility or long-term care unit. We believe that Medicaid patients receiving this skilled nursing care would on average have similar drug costs per day to dual-eligible Medicare beneficiaries who have received Medicare skilled nursing care in the skilled nursing care unit during the year. We note that our previous analysis of the Part D claims data showed that Medicare beneficiaries with a SNF stay during the year have higher drug costs than Medicare patients without a SNF stay during the year. Also, in 2018, dual-eligible beneficiaries with a SNF stay during the year had drug costs per day of $24.48, which were approximately two times higher than the drug costs per day of $13.19 for nondual-eligible beneficiaries with a SNF Part A stay during the year.

The Pharmaceuticals cost weight using only 2018 MCR data (without the inclusion of the Medicaid dual-eligible drug costs) is 2.6 percent, compared to the proposed Pharmaceuticals cost weight (including the adjustment for Medicaid dual-eligible drug costs) of 7.5 percent. The 2014-based SNF market basket had a Pharmaceuticals cost weight using only 2014 MCR data without the inclusion of the Medicaid dual-eligible drug costs of 2.9 percent and a total Pharmaceuticals cost weight of 7.3 percent. Therefore, the 0.2 percentage point increase in the Pharmaceuticals cost weight is a result of a 0.5-percentage point increase in the Medicaid dual-eligible drug cost weight (reflecting the 25 percent increase in the Medicaid dual-eligible drug costs per day between 2014 and 2018) and a 0.3-percentage point decrease in the MCR drug cost weight. The decrease in the MCR drug cost weight was consistent, in aggregate, across urban and rural status SNFs as well as across for-profit, government, and nonprofit ownership type SNFs.

(5) *Professional Liability Insurance:* We are proposing to calculate the professional liability insurance costs from Worksheet S–2 of the MCRs as the sum of premiums; paid losses; and self-insurance (Worksheet S–2, Part I, columns 1 through 3, line 41). This was the same methodology used to derive the Professional Liability costs for the 2014-based SNF market basket.

About 60 percent of SNFs (about 8,000) reported professional liability costs. After trimming, about 7,200 (reflecting about 850,000 Skilled Nursing unit beds) were included in the calculation of the Professional Liability Insurance (PLI) cost weight for the proposed 2018-based SNF market basket. These providers treated roughly 870,000 Medicare beneficiaries and had a Medicare length of stay (LOS) of 33 days, a skilled nursing unit occupancy rate of 80 percent, and an average skilled nursing unit bed size of 125 beds, which are all consistent with the national averages. We also verified that this sample of providers are representative of the national distribution of providers by ownership-type and urban/rural status. We note that the sample of providers is less consistent with the national distribution of providers by region; however, we performed a sensitivity analysis where the PLI cost weight was reweighted based on the national regional distribution and the impacts were less than a 0.1 percentage point on the cost weight.

We note that based on prior comments during the rebasing of the 2014-based SNF market basket, we reviewed in detail the AON 2018 Professional and General Liability Benchmark for Long Term Care Providers [2] that examines professional liability and general liability claim costs for long term care providers (including SNF beds, as well as independent living, assisted living, home health care, and rehabilitation facilities, representing about 186,000 long term care beds). This study, although informative, was not appropriate for calculating a PLI cost weight as it represents more than just SNFs serving Medicare patients and captures claim losses as opposed to PLI costs (premiums, paid losses, and self-insurance) incurred during a cost reporting year. We note that only 13 percent of providers reported PLI paid losses or PLI self-insurance costs on the MCR while over 90 percent of providers reported PLI premiums indicating that the majority of losses incurred by Medicare participating SNFs will be covered by insurance premiums paid over time. Our comparison of the MCR data to the AON study for those select states' data provided did show consistencies between the average state PLI costs per bed relative to the national average (as measured by the MCR) and AON's loss per occupied bed relative to national values indicating that states with higher losses per occupied bed have higher PLI costs per total bed.

We believe the MCR data continues to be the most appropriate data source to calculate the PLI cost weight for the proposed 2018-based SNF market basket as it is representative of SNFs serving Medicare beneficiaries and reflects PLI costs (premiums, paid losses, and self-insurance) incurred during the provider's cost reporting year.

(6) *Capital-Related:* We are proposing to derive the Medicare-allowable capital-related costs from Worksheet B, part II, column 18 for lines 30, 40 through 49, 51, 52, and 71. This is the same methodology to derive capital-related costs used in the 2014-based SNF market basket.

(7) *Home Office/Related Organization Contract Labor Costs:* We are proposing to calculate Medicare-allowable Home Office/Related Organization Contract Labor costs to be equal to data reported on Worksheet S–3, part II, column 3, line 16. We note that for the 2014-based SNF market basket we also used Worksheet S–3, part II, column 3, line 16 (Home office salaries & wage related costs) to determine these expenses; however, we referred to this category as Home Office Contract Labor Costs. The instructions for this data state ''enter the salaries and wage related costs (as defined on lines 17 and 18 below) paid to personnel who are affiliated with a home office and/or related organization, who *provide services to the SNF and/or NF,* and whose salaries are not included on Worksheet A, column 1,'' and therefore, we are referring to this cost category as Home Office/Related Organization Contract Labor costs. Furthermore, for this rebasing we are no longer adjusting these expenses by the ratio of Medicare allowable operating costs to total facility operating costs as done for the 2014-based SNF market basket as the instructions indicate these expenses are for the SNF and NF units.

About 7,000 providers (about 53 percent) in 2018 reported having a home office (as reported on Worksheet S–2, part I, line 45); a lower share of providers than those in the 2014-based SNF market basket. As discussed in section VI.A.1. of this proposed rule, providers without a home office can incur these expenses directly by having their own staff, for which the costs would be included in the Wages and Salaries and Employee Benefits cost weights. Alternatively, providers without a home office could also purchase related services from external contractors for which these expenses would be captured in the residual ''All-Other'' cost weight. For this reason, unlike the other major cost weights described previously, we did not exclude providers that did not report Home Office/Related Organization Contract Labor costs. We note that this is similar to the methodology that was used for other PPS market baskets such as the 2017-based LTCH market basket (85 FR 58911).

[2] *https://www.aon.com/risk-services/thought-leadership/report-2018-long-term-care.jsp.*

(8) *All Other (residual):* The ''All Other'' cost weight is a residual, calculated by subtracting the major cost weights (Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance, Capital-Related, and Home Office/Related Organization Contract Labor) from 100.

Table 12 shows the proposed major cost categories and their respective cost weights as derived from the 2018 Medicare cost reports.

TABLE 12—MAJOR COST CATEGORIES DERIVED FROM THE SNF MEDICARE COST REPORTS *

Major cost categories	Proposed 2018-based	2014-based
Wages and Salaries	44.1	44.3
Employee Benefits	8.6	9.3
Contract Labor	7.5	6.8
Pharmaceuticals	7.5	7.3
Professional Liability Insurance	1.1	1.1
Capital-related	8.2	7.9
Home Office/Related Organization Contract Labor	0.7	0.7
All other (residual)	22.3	22.6

* Total may not sum to 100 due to rounding.

Compared to the 2014-based SNF market basket, the Wages and Salaries cost weight and the Employee Benefits cost weight as calculated directly from the Medicare cost reports decreased by 0.2 percentage point and 0.7 percentage point, respectively. The Contract Labor cost weight increased 0.7 percentage point and so in aggregate, the Compensation cost weight decreased 0.2 percentage point.

As we did for the 2014-based SNF market basket (82 FR 36555), we are proposing to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2018 Medicare cost report data, this percentage is 84 percent (1 percentage point higher than the percent in the 2014-based SNF market basket); therefore, we are proposing to allocate approximately 84 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 16 percent to the Employee Benefits cost weight.

Table 13 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the proposed 2018-based SNF market basket and the 2014-based SNF market basket.

TABLE 13—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	Proposed 2018-based market basket	2014-based market basket
Wages and Salaries	50.4	50.0
Employee Benefits	9.9	10.5

b. Derivation of the Detailed Operating Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2018 Medicare cost report data into more detailed cost categories, we are proposing to use the 2012 Benchmark I–O ''Use Tables/Before Redefinitions/Purchaser Value'' for Nursing and Community Care Facilities industry (NAICS 623A00), published by the Census Bureau's, Bureau of Economic Analysis (BEA). These data are publicly available at the following website at *http://www.bea.gov/industry/io_annual.htm.* The BEA Benchmark I–O data are generally scheduled for publication every 5 years with 2012 being the most recent year for which data is available. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA's economic accounts; therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[3] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates are less comprehensive and provide less detail than benchmark data. Additionally, the annual I–O data are subject to revision once benchmark data become available. For these reasons, we propose to inflate the 2012 Benchmark I–O data aged forward to 2018 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. Next, the relative shares of the cost shares that each cost category represents to the total residual I–O costs are calculated. These resulting 2018 cost shares of the I–O data are applied to the ''All Other'' residual cost weight to obtain detailed cost weights for the residual costs for the proposed 2018-based SNF market basket. For example, the cost for Food: Direct Purchases represents 11.3 percent of the sum of the ''All Other'' 2012 Benchmark I–O Expenditures inflated to 2018. Therefore, the Food: Direct Purchases cost weight is 2.5 percent of the proposed 2018-based SNF market basket (11.3 percent × 22.3 percent = 2.5 percent). For the 2014-based SNF market basket (82 FR 36553), we used a similar methodology utilizing the 2007 Benchmark I–O data (aged to 2014).

Using this methodology, we are proposing to derive 19 detailed SNF market basket cost category weights from the proposed 2018-based SNF market basket ''All Other'' residual cost

[3] *http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

weight (22.3 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity and Other Non-Fuel Utilities; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments and Supplies; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Apparel; (10) Machinery and Equipment; (11) Miscellaneous Products; (12) Professional Fees: Labor-Related; (13) Administrative and Facilities Support Services; (14) Installation, Maintenance, and Repair Services; (15) All Other: Labor-Related Services; (16) Professional Fees: Nonlabor-Related; (17) Financial Services; (18) Telephone Services; and (19) All Other: Nonlabor-Related Services. The 2014-based SNF market basket had separate cost categories for Postage services and Water and Sewerage. Due to the small weights (less than 0.1 percentage point), we are proposing that Postage costs be included in the All Other: Non-labor-Related Services and Water and Sewerage costs be included in the Electricity and Other Non-Fuel Utilities category.

We note that the machinery and equipment expenses are for equipment that is paid for in a given year and not depreciated over the asset's useful life. Depreciation expenses for moveable equipment are accounted for in the capital component of the proposed 2018-based SNF market basket (described in section IV.A.1.c. of this proposed rule).

c. Derivation of the Detailed Capital Cost Weights

Similar to the 2014-based SNF market basket, we further divided the Capital-related cost weight into: Depreciation, Interest, Lease and Other Capital-related cost weights.

We calculated the depreciation cost weight (that is, depreciation costs excluding leasing costs) using depreciation costs from Worksheet S–2, column 1, lines 20 and 21. Since the depreciation costs reflect the entire SNF facility (Medicare and non-Medicare-allowable units), we used total facility capital costs (Worksheet B, Part I, Column 18, line 100) as the denominator. This methodology assumes that the depreciation of an asset is the same regardless of whether the asset was used for Medicare or non-Medicare patients. This methodology yielded depreciation costs as a percent of capital costs of 25.3 percent for 2018. We then apply this percentage to the proposed 2018-based SNF market basket Medicare-allowable Capital-related cost weight of 8.2 percent, yielding a Medicare-allowable depreciation cost weight (excluding leasing expenses, which is described in more detail below) of 2.1 percent. To further disaggregate the Medicare-allowable depreciation cost weight into fixed and moveable depreciation, we are proposing to use the 2018 SNF MCR data for end-of-the-year capital asset balances as reported on Worksheet A–7. The 2018 SNF MCR data showed a fixed/moveable split of 86/14. The 2014-based SNF market basket, which utilized the same data from the 2014 MCRs, had a fixed/moveable split of 83/17.

We also derived the interest expense share of capital-related expenses from 2018 SNF MCR data, specifically from Worksheet A, column 2, line 81. Similar to the depreciation cost weight, we calculated the interest cost weight using total facility capital costs. This methodology yielded interest costs as a percent of capital costs of 22.8 percent for 2018. We then apply this percentage to the proposed 2018-based SNF market basket Medicare-allowable Capital-related cost weight of 8.2 percent, yielding a Medicare-allowable interest cost weight (excluding leasing expenses) of 1.9 percent. As done with the last rebasing (82 FR 36556), we are proposing to determine the split of interest expense between for-profit and not-for-profit facilities based on the distribution of long-term debt outstanding by type of SNF (for-profit or not-for-profit/government) from the 2018 SNF MCR data. We estimated the split between for-profit and not-for-profit interest expense to be 25/75 percent compared to the 2014-based SNF market basket with 27/73 percent.

Because the detailed data were not available in the MCRs, we used the most recent 2017 Census Bureau Service Annual Survey (SAS) data to derive the capital-related expenses attributable to leasing and other capital-related expenses. The 2014-based SNF market basket used the 2014 SAS data. We note that we are proposing to use the 2017 SAS data because the Census Bureau no longer publishes these detailed capital-related expenses effective for 2018.

Based on the 2017 SAS data, we determined that leasing expenses are 62 percent of total leasing and capital-related expenses costs. In the 2014-based SNF market basket, leasing costs represent 63 percent of total leasing and capital-related expenses costs. We then apply this percentage to the proposed 2018-based SNF market basket residual Medicare-allowable capital costs of 4.2 percent derived from subtracting the Medicare-allowable depreciation cost weight and Medicare-allowable interest cost weight from the 2018-based SNF market basket of total Medicare-allowable capital cost weight (8.2 percent − 2.1 percent − 1.9 percent = 4.2 percent). This produces the proposed 2018-based SNF Medicare-allowable leasing cost weight of 2.6 percent and all-other capital-related cost weight of 1.6 percent.

Lease expenses are not broken out as a separate cost category in the SNF market basket, but are distributed among the cost categories of depreciation, interest, and other capital-related expenses, reflecting the assumption that the underlying cost structure and price movement of leasing expenses is similar to capital costs in general. As was done with past SNF market baskets and other PPS market baskets, we assumed 10 percent of lease expenses are overhead and assigned them to the other capital-related expenses cost category. This is based on the assumption that leasing expenses include not only depreciation, interest, and other capital-related costs but also additional costs paid to the lessor. We distributed the remaining lease expenses to the three cost categories based on the proportion of depreciation, interest, and other capital-related expenses to total capital costs, excluding lease expenses.

Table 14 shows the capital-related expense distribution (including expenses from leases) in the proposed 2018-based SNF market basket and the 2014-based SNF market basket.

TABLE 14—COMPARISON OF THE CAPITAL-RELATED EXPENSE DISTRIBUTION OF THE PROPOSED 2018-BASED SNF MARKET BASKET AND THE 2014-BASED SNF MARKET BASKET

Cost category	Proposed 2018-based SNF market basket	2014-based SNF market basket
Capital-related Expenses	8.2	7.9
Total Depreciation	3.0	2.9

TABLE 14—COMPARISON OF THE CAPITAL-RELATED EXPENSE DISTRIBUTION OF THE PROPOSED 2018-BASED SNF MARKET BASKET AND THE 2014-BASED SNF MARKET BASKET—Continued

Cost category	Proposed 2018-based SNF market basket	2014-based SNF market basket
Total Interest	2.7	3.0
Other Capital-related Expenses	2.6	2.0

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail capital cost weights may not add to the total capital-related expenses cost weight due to rounding.

Table 15 presents the proposed 2018-based SNF market basket and the 2014-based SNF market basket.

TABLE 15—PROPOSED 2018-BASED SNF MARKET BASKET AND 2014-BASED SNF MARKET BASKET

Cost category	Proposed 2018-based SNF market basket	2014-Based SNF market basket
Total	100.0	100.0
Compensation	60.2	60.4
Wages and Salaries [1]	50.4	50.0
Employee Benefits [1]	9.9	10.5
Utilities	1.5	2.6
Electricity and Other Non-Fuel Utilities	1.0	1.4
Fuel: Oil and Gas	0.4	1.3
Professional Liability Insurance	1.1	1.1
All Other	29.0	27.9
Other Products	17.6	14.3
Pharmaceuticals	7.5	7.3
Food: Direct Purchase	2.5	3.1
Food: Contract Purchase	4.3	0.7
Chemicals	0.2	0.2
Medical Instruments and Supplies	0.6	0.6
Rubber and Plastics	0.7	0.8
Paper and Printing Products	0.5	0.8
Apparel	0.5	0.3
Machinery and Equipment	0.5	0.3
Miscellaneous Products	0.3	0.3
All Other Services	11.5	13.6
Labor-Related Services	6.4	7.4
Professional Fees: Labor-related	3.5	3.8
Installation, Maintenance, and Repair Services	0.6	0.6
Administrative and Facilities Support	0.4	0.5
All Other: Labor-Related Services	1.9	2.5
Non Labor-Related Services	5.1	6.2
Professional Fees: Nonlabor-Related	2.0	1.8
Financial Services	1.3	2.0
Telephone Services	0.3	0.5
All Other: Nonlabor-Related Services [3]	1.5	2.0
Capital-Related Expenses	8.2	7.9
Total Depreciation	3.0	2.9
Building and Fixed Equipment	2.5	2.5
Movable Equipment	0.4	0.4
Total Interest	2.7	3.0
For-Profit SNFs	0.7	0.8
Government and Nonprofit SNFs	2.0	2.1
Other Capital-Related Expenses	2.6	2.0

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

[2] Water and Sewerage costs are included in the Electricity and Other Non-Fuel Utilities cost category in the proposed 2018-based SNF market basket.

[3] Postage costs are included in the All Other Non-labor-related cost category in the proposed 2018-based SNF market basket.

2. Price Proxies Used To Measure Operating Cost Category Growth

After developing the 27 cost weights for the proposed 2018-based SNF market basket, we selected the most appropriate wage and price proxies currently available to represent the rate of change for each expenditure category. With four exceptions (three for the capital-related expenses cost categories and one for Professional Liability Insurance (PLI)), we base the wage and price proxies on Bureau of Labor Statistics (BLS) data, and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the 2012 NAICS and the occupational ECIs are based on the 2000 and 2010 Standard Occupational Classification System (SOC).
- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.) Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis. Finally, relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Table 20 lists all price proxies for the proposed 2018-based SNF market basket. Below is a detailed explanation of the price proxies used for each operating cost category.

- *Wages and Salaries:* We are proposing to use the ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities (NAICS 6231; BLS series code CIU2026231000000I) to measure price growth of this category. NAICS 623 includes facilities that provide a mix of health and social services, with many of the health services being largely some level of nursing services. Within NAICS 623 is NAICS 6231, which includes nursing care facilities primarily engaged in providing inpatient nursing and rehabilitative services. These facilities, which are most comparable to Medicare-certified SNFs, provide skilled nursing and continuous personal care services for an extended period of time, and, therefore, have a permanent core staff of registered or licensed practical nurses. This is the same index used in the 2014-based SNF market basket.
- *Employee Benefits:* We are proposing to use the ECI for Benefits for Nursing Care Facilities (NAICS 6231) to measure price growth of this category. The ECI for Benefits for Nursing Care Facilities is calculated using BLS's total compensation (BLS series ID CIU2016231000000I) for nursing care facilities series and the relative importance of wages and salaries within total compensation. We believe this constructed ECI series is technically appropriate for the reason stated above in the Wages and Salaries price proxy section. This is the same index used in the 2014-based SNF market basket.
- *Electricity and Other Non-Fuel Utilities:* We are proposing to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category as Electricity costs account for 93 percent of these expenses. This is the same index used for the Electricity cost category in the 2014-based SNF market basket. As previously noted, we are proposing to include Water and Sewerage costs within the Electricity and Other Non-Fuel Utilities cost category, and to no longer use the CPI All Urban for Water and Sewerage Maintenance as we did for the 2014-based SNF market basket, due to the small size of this estimated cost weight (less than 0.1 percent).
- *Fuel: Oil and Gas:* We are proposing to change the proxy used for the Fuel: Oil and Gas cost category. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark I–O data for Nursing and Community Care Facilities shows approximately 96 percent of SNF Fuel: Oil and Gas expenses are for Petroleum Refineries (NAICS 324110), Natural gas (NAICS 221200), and Other Petroleum and Coal Products Manufacturing (NAICS 324190). We are proposing to create a blended index based on those three NAICS chemical expenses listed above that account for 96 percent of SNF chemical expenses. We are proposing to create this blend based on each NAICS' expenses as a share of their sum. Therefore, we are proposing a blended proxy of 61 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU32411–32411), 7 percent of the PPI Commodity for Natural Gas (BLS series code WPU0531), and 32 percent of the PPI for Other Petroleum and Coal Products manufacturing (BLS series code PCU32419–32419).

The 2014-based SNF market basket also used a blended chemical proxy that was based on 2007 Benchmark I–O data. We believe our proposed Fuel: Oil and Gas blended index for the 2018-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 16 provides the weights for the proposed 2018-based blended chemical index and the 2014-based blended chemical index.

TABLE 16—PROPOSED FUEL: OIL AND GAS BLENDED INDEX WEIGHTS

NAICS	Price proxy	Proposed 2018-based index (%)	2014-based index (%)
221200	PPI Commodity for Natural Gas	7	35
324110	PPI Industry for Petroleum Refineries	61	65
324190	PPI for Other Petroleum and Coal Products manufacturing	32	n/a
Total	.....	100	100

• *Professional Liability Insurance:* We are proposing to use the CMS Hospital Professional Liability Insurance Index to measure price growth of this category. We were unable to find a reliable data source that collects SNF-specific PLI data. Therefore, we are proposing to use the CMS Hospital Professional Liability Index, which tracks price changes for commercial insurance premiums for a fixed level of coverage, holding non-price factors constant (such as a change in the level of coverage). This is the same index used in the 2014-based SNF market basket. We believe this is an appropriate proxy to measure the price growth associated of SNF professional liability insurance as it captures the price inflation associated with other medical institutions that serve Medicare patients.

• *Pharmaceuticals:* We are proposing to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Food: Wholesale Purchases:* We are proposing to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Food: Retail Purchase:* We are proposing to use the CPI All Urban for Food Away From Home (All Urban Consumers) (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Chemicals:* For measuring price change in the Chemicals cost category, we are proposing to use a blended PPI composed of the Industry PPIs for Other Basic Organic Chemical Manufacturing (NAICS 325190) (BLS series code PCU32519–32519), Soap and Cleaning Compound Manufacturing (NAICS 325610) (BLS series code PCU32561–32561), and Other Miscellaneous Chemical Product Manufacturing (NAICS 325998) (BLS series code PCU325998325998).

Using the 2012 Benchmark I–O data, we found that these three NAICS industries accounted for approximately 96 percent of SNF chemical expenses. The remaining four percent of SNF chemical expenses are for three other incidental NAICS chemicals industries such as Paint and Coating Manufacturing. We are proposing to create a blended index based on those three NAICS chemical expenses listed above that account for 96 percent of SNF chemical expenses. We are proposing to create this blend based on each NAICS' expenses as a share of their sum. These expenses as a share of their sum are listed in Table 17.

The 2014-based SNF market basket also used a blended chemical proxy that was based on 2007 Benchmark I–O data. We believe our proposed chemical blended index for the 2018-based SNF market basket is technically appropriate as it reflects more recent data on SNFs purchasing patterns. Table 17 provides the weights for the proposed 2018-based blended chemical index and the 2014-based blended chemical index.

TABLE 17—PROPOSED CHEMICAL BLENDED INDEX WEIGHTS

NAICS	Price proxy	Proposed 2018-based index (%)	2014-based index (%)
325190	PPI for Other Basic Organic Chemical Manufacturing	34	22
325610	PPI for Soap and Cleaning Compound Manufacturing	21	37
325998	PPI for Other Miscellaneous Chemical Product Manufacturing	45	41
Total	.....	100	100

• *Medical Instruments and Supplies:* We are proposing to change the proxy used for the Medical Instruments and Supplies cost weight. The 2012 Benchmark I–O data shows 46 percent of medical instruments and supply costs are for Surgical and medical instrument manufacturing costs (NAICS 339112) and 54 percent are for Surgical appliance and supplies manufacturing costs (NAICS 339113). To proxy the price changes associated with NAICS 339112, we propose using the PPI—Commodity—Surgical and medical instruments (BLS series code WPU1562). This the same price proxy we used in the 2014-based SNF market basket. To proxy the price changes associated with NAICS 339113, we are proposing to use 50 percent for the PPI—Commodity—Medical and surgical appliances and supplies (BLS series code WPU1563) and 50 percent for the PPI Commodity data for Miscellaneous products-Personal safety equipment and clothing (BLS series code WPU1571). The latter price proxy would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific expenses for personal protective equipment (which would be reflected in the NAICS 339113 expenses); however, we recognize that this category reflects costs faced by SNFs. In absence of any specific cost data on personal protective equipment, we are proposing to include the PPI Commodity data for

Miscellaneous products-Personal safety equipment and clothing (BLS series code WPU1571) in the blended proxy for Medical Instruments and Supplies cost category with a weight of 27 percent (that is, 50 percent of the NAICS 339113 expenses as a percent of the sum of NAICS 339113 and NAICS 339112 expenses from the I–O).

The 2014-based SNF market basket used a blend composed of 60 percent of the PPI Commodity for Medical and Surgical Appliances and Supplies (BLS series code WPU1563) and 40 percent of the PPI Commodity for Surgical and Medical Instruments (BLS series code WPU1562). Table 18 provides the proposed Medical Instruments and Supplies cost weight blended price proxy.

TABLE 18—PROPOSED MEDICAL INSTRUMENTS AND SUPPLIES BLENDED INDEX WEIGHTS

NAICS	Price proxy	Proposed 2018-based index (%)	2014-based index (%)
339112	PPI—Commodity—Surgical and medical instruments (WUI1562)	46	40
339113	PPI—Commodity—Medical and surgical appliances and supplies (WPU1563)	27	60
	PPI Commodity data for Miscellaneous products—Personal safety equipment and clothing (WPU1571).	27	n/a
Total	.....	100	100

• *Rubber and Plastics:* We are proposing to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Paper and Printing Products:* We are proposing to use the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• Apparel: We are proposing to use the PPI Commodity for Apparel (BLS series code WPU0381) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Machinery and Equipment:* We are proposing to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Miscellaneous Products:* For measuring price change in the Miscellaneous Products cost category, we are proposing to use the PPI Commodity for Finished Goods less Food and Energy (BLS series code WPUFD4131). Both food and energy are already adequately represented in separate cost categories and should not also be reflected in this cost category. This is the same index used in the 2014-based SNF market basket.

• *Professional Fees: Labor-Related:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the 2014-based SNF market basket.

• *Administrative and Facilities Support Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same index used in the 2014-based SNF market basket.

• *Installation, Maintenance and Repair Services:* We are proposing to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU10100004300001) to measure the price growth of this new cost category. This is the same index used in the 2014-based SNF market basket.

• *All Other: Labor-Related Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Professional Fees: NonLabor-Related:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same index used in the 2014-based SNF market basket.

• *Financial Services:* We are proposing to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *Telephone Services:* We are proposing to use the CPI All Urban for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket.

• *All Other: NonLabor-Related Services:* We are proposing to use the CPI All Urban for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same index used in the 2014-based SNF market basket. As previously noted, we are proposing to include Postage costs within the All Other: NonLabor-Related Services cost category, and to no longer use the CPI All Urban for Postage as we did for the 2014-based SNF market basket, due to the small size of this estimated cost weight (less than 0.1 percent).

3. Price Proxies Used To Measure Capital Cost Category Growth

We are proposing to apply the same capital price proxies as were used in the 2014-based SNF market basket, with the exception of the For-profit interest cost category, and below is a detailed explanation of the price proxies used for each capital cost category. We also are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same method that was used for the 2014-based SNF market basket and is described below.

• *Depreciation—Building and Fixed Equipment:* We are proposing to use the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type). This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing

homes, hospices, and rehabilitation centers. This is the same index used in the 2014-based SNF market basket.

- *Depreciation—Movable Equipment:* We are proposing to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11). This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by SNFs including but not limited to medical equipment, communication equipment, and computers. This is the same index used in the 2014-based SNF market basket.
- *Nonprofit Interest:* We are proposing to use the average yield on Municipal Bonds (Bond Buyer 20-bond index). This is the same index used in the 2014-based SNF market basket.
- *For-Profit Interest:* For the For-Profit Interest cost category, we are proposing to use the iBoxx AAA Corporate Bond Yield index instead of the Moody's AAA Corporate Bond Yield index that was used for the 2014-based SNF market basket. Effective for December 2020, the Moody's AAA Corporate Bond series is no longer available for use under license to IGI, the nationally-recognized economic and financial forecasting firm with whom we contract to forecast the components of the market baskets and MFP. Therefore, we are proposing to replace the price proxy for the For-Profit interest cost category. We compared the iBoxx AAA Corporate Bond Yield index with the Moody's AAA Corporate Bond Yield index and found that the average growth rates in the two series were similar. Over the historical time period of FY 2000 to FY 2020, the 4-quarter percent change moving average growth in the iBoxx series was approximately 0.1 percentage point higher, on average, than the Moody's AAA corporate Bond Yield index.
- *Other Capital:* Since this category includes fees for insurances, taxes, and other capital-related costs, we are proposing to use the CPI for Rent of Primary Residence (BLS series code CUUS0000SEHA), which would reflect the price growth of these costs. This is the same index used in the 2014-based SNF market basket.

We believe that these price proxies are the most appropriate proxies for SNF capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

As stated above, we are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. To capture the long-term nature, the price proxies are vintage-weighted; and the vintage weights are calculated using a two-step process. First, we determine the expected useful life of capital and debt instruments held by SNFs. Second, we identify the proportion of expenditures within a cost category that is attributable to each individual year over the useful life of the relevant capital assets, or the vintage weights.

We rely on Bureau of Economic Analysis (BEA) fixed asset data to derive the useful lives of both fixed and movable capital, which is the same data source used to derive the useful lives for the 2014-based SNF market basket. The specifics of the data sources used are explained below.

a. Calculating Useful Lives for Moveable and Fixed Assets

Estimates of useful lives for movable and fixed assets for the proposed 2018-based SNF market basket are 9 and 26 years, respectively. These estimates are based on three data sources from the BEA: (1) Current-cost average age; (2) historical-cost average age; and (3) industry-specific current cost net stocks of assets.

BEA current-cost and historical-cost average age data by asset type are not available by industry but are published at the aggregate level for all industries. The BEA does publish current-cost net capital stocks at the detailed asset level for specific industries. There are 64 detailed movable assets (including intellectual property) and there are 32 detailed fixed assets in the BEA estimates. Since we seek aggregate useful life estimates applicable to SNFs, we developed a methodology to approximate movable and fixed asset ages for nursing and residential care services (NAICS 623) using the published BEA data. For the proposed 2018 SNF market basket, we use the current-cost average age for each asset type from the BEA fixed assets Table 2.9 for all assets and weight them using current-cost net stock levels for each of these asset types in the nursing and residential care services industry, NAICS 6230. (For example, nonelectro medical equipment current-cost net stock (accounting for about 35 percent of total moveable equipment current-cost net stock in 2018) is multiplied by an average age of 4.7 years. Current-cost net stock levels are available for download from the BEA website at *https://apps.bea.gov/iTable/index_FA.cfm.* We then aggregate the ''weighted'' current-cost net stock levels (average age multiplied by current-cost net stock) into moveable and fixed assets for NAICS 6230. We then adjust the average ages for moveable and fixed assets by the ratio of historical-cost average age (Table 2.10) to current-cost average age (Table 2.9).

This produces historical cost average age data for movable (equipment and intellectual property) and fixed (structures) assets specific to NAICS 6230 of 4.7 and 13.1 years for 2018, respectively. The average age reflects the average age of an asset at a given point in time, whereas we want to estimate a useful life of the asset, which would reflect the average over all periods an asset is used. To do this, we multiply each of the average age estimates by two to convert to average useful lives with the assumption that the average age is normally distributed (about half of the assets are below the average at a given point in time, and half above the average at a given point in time). This produces estimates of likely useful lives of 9.49 and 26.19 years for movable and fixed assets, which we round to 9 and 26 years, respectively. We are proposing an interest vintage weight time span of 24 years, obtained by weighting the fixed and movable vintage weights (26 years and 9 years, respectively) by the fixed and movable split (86 percent and 14 percent, respectively). This is the same methodology used for the 2014-based SNF market basket, which had useful lives of 23 years and 10 years for fixed and moveable assets, respectively. We estimate that the impact of revising the useful lives had a minor impact on the average historical growth rate of the proposed 2018-based SNF market basket total aggregate capital cost price proxy. Over the FY 2016 to FY 2020 time period, the percent change moving average in the total aggregate capital cost price proxy was about 0.06 percentage point higher, on average, based on the proposed 2018-based SNF market basket compared to the 2014-based SNF market basket.

b. Constructing Vintage Weights

Given the expected useful life of capital (fixed and moveable assets) and debt instruments, we must determine the proportion of capital expenditures attributable to each year of the expected useful life for each of the three asset types: Building and fixed equipment, moveable equipment, and interest. These proportions represent the vintage weights. We were not able to find a historical time series of capital expenditures by SNFs. Therefore, we approximated the capital expenditure patterns of SNFs over time, using alternative SNF data sources. For building and fixed equipment, we used the stock of beds in nursing homes from the National Nursing Home Survey (NNHS) conducted by the National

Center for Health Statistics (NCHS) for 1962 through 1999. For 2000 through 2010, we extrapolated the 1999 bed data forward using a 5-year moving average of growth in the number of beds from the SNF MCR data. For 2011 to 2014, we extrapolate the 2010 bed data forward using the average growth in the number of beds over the 2011 to 2014 time period. For 2015 to 2018, we propose to extrapolate the 2014 bed data forward using the average growth in the number of beds over the 2015 to 2018 time period. We then used the change in the stock of beds each year to approximate building and fixed equipment purchases for that year. This procedure assumes that bed growth reflects the growth in capital-related costs in SNFs for building and fixed equipment. We believe that this assumption is reasonable because the number of beds reflects the size of a SNF, and as a SNF adds beds, it also likely adds fixed capital.

As was done for the 2014-based SNF market basket (as well as prior market baskets), we are proposing to estimate moveable equipment purchases based on the ratio of ancillary costs to routine costs. The time series of the ratio of ancillary costs to routine costs for SNFs measures changes in intensity in SNF services, which are assumed to be associated with movable equipment purchase patterns. The assumption here is that as ancillary costs increase compared to routine costs, the SNF caseload becomes more complex and would require more movable equipment. The lack of movable equipment purchase data for SNFs over time required us to use alternative SNF data sources. A more detailed discussion of this methodology was published in the FY 2008 SNF final rule (72 FR 43428). We believe the resulting two time series, determined from beds and the ratio of ancillary to routine costs, reflect real capital purchases of building and fixed equipment and movable equipment over time.

To obtain nominal purchases, which are used to determine the vintage weights for interest, we converted the two real capital purchase series from 1963 through 2018 determined above to nominal capital purchase series using their respective price proxies (the BEA Chained Price Index for Nonresidential Construction for Hospitals & Special Care Facilities and the PPI for Machinery and Equipment). We then combined the two nominal series into one nominal capital purchase series for 1963 through 2018. Nominal capital purchases are needed for interest vintage weights to capture the value of debt instruments.

Once we created these capital purchase time series for 1963 through 2018, we averaged different periods to obtain an average capital purchase pattern over time: (1) For building and fixed equipment, we averaged 31, 26-year periods; (2) for movable equipment, we averaged 48, 9-year periods; and (3) for interest, we averaged 33, 24-year periods. We calculate the vintage weight for a given year by dividing the capital purchase amount in any given year by the total amount of purchases during the expected useful life of the equipment or debt instrument. To provide greater transparency, we posted on the CMS market basket website at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html,* an illustrative spreadsheet that contains an example of how the vintage-weighted price indexes are calculated.

The vintage weights for the proposed 2018-based SNF market basket and the 2014-based SNF market basket are presented in Table 19.

TABLE 19—PROPOSED 2018-BASED VINTAGE WEIGHTS AND 2014-BASED VINTAGE WEIGHTS

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	Proposed 2018-based 26 years	2014-Based 23 years	Proposed 2018-based 9 years	2014-Based 10 years	Proposed 2018-based 24 years	2014-Based 21 years
1	0.049	0.056	0.135	0.085	0.027	0.032
2	0.050	0.055	0.140	0.087	0.028	0.033
3	0.049	0.054	0.128	0.091	0.029	0.034
4	0.047	0.052	0.112	0.097	0.031	0.036
5	0.045	0.049	0.119	0.099	0.032	0.037
6	0.043	0.046	0.111	0.102	0.034	0.039
7	0.041	0.044	0.084	0.108	0.036	0.041
8	0.040	0.043	0.080	0.109	0.037	0.043
9	0.037	0.040	0.091	0.110	0.038	0.044
10	0.035	0.038	.....	0.112	0.040	0.045
11	0.036	0.038	.....	.....	0.043	0.048
12	0.036	0.039	.....	.....	0.047	0.052
13	0.036	0.039	.....	.....	0.049	0.056
14	0.036	0.039	.....	.....	0.051	0.058
15	0.035	0.039	.....	.....	0.050	0.060
16	0.036	0.039	.....	.....	0.048	0.059
17	0.036	0.040	.....	.....	0.048	0.057
18	0.038	0.041	.....	.....	0.048	0.057
19	0.037	0.043	.....	.....	0.048	0.056
20	0.036	0.042	.....	.....	0.048	0.056
21	0.035	0.042	.....	.....	0.047	0.057
22	0.035	0.042	.....	.....	0.047	.....
23	0.035	0.042	.....	.....	0.047	.....
24	0.033	.....	.....	.....	0.049	.....
25	0.032	.....	.....	.....	.....	.....
26	0.032	.....	.....	.....	.....	.....

TABLE 19—PROPOSED 2018-BASED VINTAGE WEIGHTS AND 2014-BASED VINTAGE WEIGHTS—Continued

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	Proposed 2018-based 26 years	2014-Based 23 years	Proposed 2018-based 9 years	2014-Based 10 years	Proposed 2018-based 24 years	2014-Based 21 years
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: The vintage weights are calculated using thirteen decimals. For presentation purposes, we are displaying three decimals and therefore, the detail vintage weights may not add to 1.000 due to rounding.

[1] Year 1 represents the vintage weight applied to the farthest year while the vintage weight for year 26, for example, would apply to the most recent year.

Table 20 shows all the price proxies for the proposed 2018-based SNF market basket.

TABLE 20—PROPOSED PRICE PROXIES FOR THE PROPOSED 2018-BASED SNF MARKET BASKET

Cost category	Weight	Proposed price proxy
Total	100.0	
Compensation	60.2	
Wages and Salaries [1]	50.4	ECI for Wages and Salaries for Private Industry Workers in Nursing Care Facilities.
Employee Benefits [1]	9.9	ECI for Total Benefits for Private Industry Workers in Nursing Care Facilities.
Utilities	1.5	
Electricity and Other Non-Fuel Utilities	1.0	PPI Commodity for Commercial Electric Power.
Fuel: Oil and Gas	0.4	Blend of Fuel PPIs.
Professional Liability Insurance	1.1	CMS Professional Liability Insurance Premium Index.
All Other	29.0	
Other Products	17.6	
Pharmaceuticals	7.5	PPI Commodity for Pharmaceuticals for Human Use, Prescription.
Food: Direct Purchase	2.5	PPI Commodity for Processed Foods and Feeds.
Food: Contract Purchase	4.3	CPI for Food Away From Home (All Urban Consumers).
Chemicals	0.2	Blend of Chemical PPIs.
Medical Instruments and Supplies	0.6	Blend of Medical Instruments and Supplies PPIs.
Rubber and Plastics	0.7	PPI Commodity for Rubber and Plastic Products.
Paper and Printing Products	0.5	PPI Commodity for Converted Paper and Paperboard Products.
Apparel	0.5	PPI Commodity for Apparel.
Machinery and Equipment	0.5	PPI Commodity for Machinery and Equipment.
Miscellaneous Products	0.3	PPI Commodity for Finished Goods Less Food and Energy.
All Other Services	11.5	
Labor-Related Services	6.4	
Professional Fees: Labor-related	3.5	ECI for Total Compensation for Private Industry Workers in Professional and Related.
Installation, Maintenance, and Repair Services	0.6	ECI for Total Compensation for All Civilian workers in Installation, Maintenance, and Repair.
Administrative and Facilities Support	0.4	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.
All Other: Labor-Related Services	1.9	ECI for Total Compensation for Private Industry Workers in Service Occupations.
Non Labor-Related Services	5.1	
Professional Fees: Nonlabor-Related	2.0	ECI for Total Compensation for Private Industry Workers in Professional and Related.
Financial Services	1.3	ECI for Total Compensation for Private Industry Workers in Financial Activities.
Telephone Services	0.3	CPI for Telephone Services.
All Other: Nonlabor-Related Services	1.5	CPI for All Items Less Food and Energy.
Capital-Related Expenses	8.2	
Total Depreciation	3.0	
Building and Fixed Equipment	2.5	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care—vintage weighted 26 years.
Movable Equipment	0.4	PPI Commodity for Machinery and Equipment—vintage weighted 9 years.
Total Interest	2.7	

TABLE 20—PROPOSED PRICE PROXIES FOR THE PROPOSED 2018-BASED SNF MARKET BASKET—Continued

Cost category	Weight	Proposed price proxy
For-Profit SNFs	0.7	iBoxx—Average yield on Aaa bond—vintage weighted 24 years.
Government and Nonprofit SNFs	2.0	Bond Buyer—Average yield on Domestic Municipal Bonds—vintage weighted 24 years.
Other Capital-Related Expenses	2.6	CPI for Rent of Primary Residence.

Note: The cost weights are calculated using three decimal places. For presentation purposes, we are displaying one decimal and, therefore, the detailed cost weights may not add to the aggregate cost weights or to 100.0 due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

4. Labor-Related Share

We define the labor-related share (LRS) as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. Each year, we calculate a revised labor-related share based on the relative importance of labor-related cost categories in the input price index. Effective for FY 2022, we are proposing to revise and update the labor-related share to reflect the relative importance of the proposed 2018-based SNF market basket cost categories that we believe are labor-intensive and vary with, or are influenced by, the local labor market. For the proposed 2018-based SNF market basket these are: (1) Wages and Salaries (including allocated contract labor costs as described above); (2) Employee Benefits (including allocated contract labor costs as described above); (3) Professional fees: Labor-related; (4) Administrative and Facilities Support Services; (5) Installation, Maintenance, and Repair Services; (6) All Other: Labor-Related Services; and (7) a proportion of capital-related expenses. We propose to continue to include a proportion of capital-related expenses because a portion of these expenses are deemed to be labor-intensive and vary with, or are influenced by, the local labor market. For example, a proportion of construction costs for a medical building would be attributable to local construction workers' compensation expenses.

Consistent with previous SNF market basket revisions and rebasings, the All Other: Labor-related services cost category is mostly comprised of building maintenance and security services (including, but not limited to, landscaping services, janitorial services, waste management services services) and dry cleaning and laundry services. Because these services tend to be labor-intensive and are mostly performed at the SNF facility or in the local area (and therefore, unlikely to be purchased in the national market), we believe that they meet our definition of labor-related services.

These are the same cost categories we have included in the LRS for the 2014-based SNF market basket rebasing (82 FR 36563) as well as the same categories included in the LRS for the 2016-based IRF market basket (84 FR 39087), 2016-based IPF market basket (84 FR 38445), and 2017-based LTCH market basket (85 FR 58910).

As discussed in the FY 2018 SNF PPS proposed rule (82 FR 21040), in an effort to determine more accurately the share of nonmedical professional fees (included in the proposed 2018-based SNF market basket Professional Fees cost categories) that should be included in the labor-related share, we surveyed SNFs regarding the proportion of those fees that are attributable to local firms and the proportion that are purchased from national firms. Based on these weighted results, we determined that SNFs purchase, on average, the following portions of contracted professional services inside their local labor market:

- 78 percent of legal services.
- 86 percent of accounting and auditing services.
- 89 percent of architectural, engineering services.
- 87 percent of management consulting services.

Together, these four categories represent 3.5 percentage points of the total costs for the proposed 2018-based SNF market basket. We applied the percentages from this special survey to their respective SNF market basket weights to separate them into labor-related and nonlabor-related costs. As a result, we are designating 2.9 of the 3.5 percentage points total to the labor-related share, with the remaining 0.6 percentage point categorized as nonlabor-related.

In addition to the professional services as previously listed, for the 2018-based SNF market basket, we propose to allocate a proportion of the Home Office/Related Organization Contract Labor cost weight, calculated using the Medicare cost reports as previously stated, into the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost categories. We propose to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office and, therefore, do not meet our definition for the labor-related share that requires the services to be purchased in the local labor market.

Similar to the 2014-based SNF market basket, we propose for the 2018-based SNF market basket to use the Medicare cost reports for SNFs to determine the home office labor-related percentages. The Medicare cost report requires a SNF to report information regarding their home office provider. Using information on the Medicare cost report, we compared the location of the SNF with the location of the SNF's home office. We propose to classify a SNF with a home office located in their respective labor market if the SNF and its home office are located in the same Metropolitan Statistical Area (MSA). Then we determine the proportion of the Home Office/Related Organization Contract Labor cost weight that should be allocated to the labor-related share based on the percent of total Home Office/Related Organization Contract Labor costs for those SNFs that had home offices located in their respective local labor markets of total Home Office/Related Organization Contract Labor costs for SNFs with a home office. We determined a SNF's and its home office's MSA using their zip code information from the Medicare cost report. Using this methodology, we determined that 21 percent of SNFs' Home Office/Related Organization Contract Labor costs were for home offices located in their respective local labor markets. Therefore, we propose to allocate 21 percent of the Home Office/Related Organization Contract Labor cost weight (0.14 percentage point = 0.69 percent × 21 percent) to the Professional Fees: Labor-related cost weight and 79 percent of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-related cost weight (0.55

percentage point = 0.69 percent × 79 percent). The 2014-based SNF market basket used a similar methodology for allocating the Home Office/Related Organization Contract Labor cost weight to the labor-related share.

In summary, based on the two allocations mentioned earlier, we propose to apportion 3.0 percentage points of the Professional Fees (2.9 percentage points) and Home Office/Related Organization Contract Labor (0.1 percentage point) cost weights into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that we already identified as labor-related using the I–O data such as contracted advertising and marketing costs (approximately 0.45 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 3.5 percent.

Table 21 compares the FY 2022 labor-related share based on the proposed 2018-based SNF market basket relative importance and the FY 2021 labor-related share based on the 2014-based SNF market basket relative importance as finalized in the FY 2021 SNF final rule (85 FR 47605).

TABLE 21—FY 2021 AND PROPOSED FY 2022 SNF LABOR-RELATED SHARE

	Relative importance, labor-related share, FY 2021 20:2 forecast [1]	Proposed relative importance, labor-related share, FY 2022 20:4 forecast [2]
Wages and salaries [3]	51.1	51.2
Employee benefits*	9.9	9.5
Professional fees: Labor-related	3.7	3.5
Administrative & facilities support services	0.5	0.6
Installation, maintenance & repair services	0.6	0.4
All other: Labor-related services	2.6	1.9
Capital-related (.391)	2.9	3.0
Total	71.3	70.1

[1] Published in the **Federal Register** (85 FR 47605); based on the second quarter 2020 IHS Global Inc. forecast of the 2014-based SNF market basket, with historical data through first quarter 2020.
[2] Based on the fourth quarter 2020 IHS Global Inc. forecast of the proposed 2018-based SNF market basket.
[3] The Wages and Salaries and Employee Benefits cost weight reflect contract labor costs as described above.

The proposed FY 2022 SNF labor-related share is 1.2 percentage points lower than the FY 2021 SNF labor-related share (based on the 2014-based SNF market basket). The major reason for the lower labor-related share is due to the incorporation of the 2012 Benchmark I–O data, primarily stemming from a decrease in the All Other: Labor-related services and Professional Fees: Labor-related services cost weights, and a decrease in the Compensation cost weight as a result of incorporating the 2018 MCR data.

5. Proposed Market Basket Estimate for the FY 2022 SNF PPS Update

As discussed previously in this proposed rule, beginning with the FY 2022 SNF PPS update, we are proposing to adopt the 2018-based SNF market basket as the appropriate market basket of goods and services for the SNF PPS. Consistent with historical practice, we estimate the market basket update for the SNF PPS based on IHS Global Inc.'s (IGI) forecast. IGI is a nationally recognized economic and financial forecasting firm that contracts with CMS to forecast the components of the market baskets and multifactor productivity (MFP). Based on IGI's fourth quarter 2020 forecast with historical data through the third quarter of 2020, the most recent estimate of the proposed 2018-based SNF market basket update for FY 2022 is 2.3 percent − 0.1 percentage point lower (after rounding) than the FY 2022 percent change of the 2014-based SNF market basket. We are also proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket and/or the MFP), we would use such data, if appropriate, to determine the FY 2022 SNF market basket percentage change, labor-related share relative importance, forecast error adjustment, or MFP adjustment in the SNF PPS final rule.

Table 22 compares the proposed 2018-based SNF market basket and the 2014-based SNF market basket percent changes. For the historical period between FY 2017 and FY 2020, there is no difference in the average growth rates between the two market baskets. For the forecasted period between FY 2021 and FY 2023, the average difference between the two market baskets is −0.1 percentage point.

TABLE 22—PROPOSED 2018-BASED SNF MARKET BASKET AND 2014-BASED SNF MARKET BASKET, PERCENT CHANGES: 2017–2023

Fiscal year (FY)	Proposed 2018-Based SNF market basket	2014-Based SNF market basket
Historical data:		
FY 2017	2.5	2.7
FY 2018	2.6	2.6
FY 2019	2.4	2.3
FY 2020	2.1	2.0
Average FY 2017–2020	2.4	2.4
Forecast:		
FY 2021	2.4	2.4
FY 2022	2.3	2.4

TABLE 22—PROPOSED 2018-BASED SNF MARKET BASKET AND 2014-BASED SNF MARKET BASKET, PERCENT CHANGES: 2017–2023—Continued

Fiscal year (FY)	Proposed 2018-Based SNF market basket	2014-Based SNF market basket
FY 2023	2.6	2.7
Average FY 2021–2023	2.4	2.5

Source: IHS Global, Inc. 4th quarter 2020 forecast with historical data through 3rd quarter 2020.

B. Technical Updates to PDPM ICD–10 Mappings

In the FY 2019 SNF PPS final rule (83 FR 39162), we finalized the implementation of the Patient Driven Payment Model (PDPM), effective October 1, 2019. The PDPM utilizes International Classification of Diseases, Version 10 (ICD–10) codes in several ways, including to assign patients to clinical categories used for categorization under several PDPM components, specifically the PT, OT, SLP and NTA components. The ICD–10 code mappings and lists used under PDPM are available on the PDPM website at *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/SNFPPS/PDPM.*

Each year, the ICD–10 Coordination and Maintenance Committee, a Federal interdepartmental committee that is chaired by representatives from the National Center for Health Statistics (NCHS) and by representatives from CMS, meets biannually and publishes updates to the ICD–10 medical code data sets in June of each year. These changes become effective October 1 of the year in which these updates are issued by the committee. The ICD–10 Coordination and Maintenance Committee also has the ability to make changes to the ICD–10 medical code data sets effective on April 1.

In the FY 2020 SNF PPS final rule (84 FR 38750), we outlined the process by which we maintain and update the ICD–10 code mappings and lists associated with the PDPM, as well as the SNF GROUPER software and other such products related to patient classification and billing, so as to ensure that they reflect the most up to date codes possible. Beginning with the updates for FY 2020, we apply nonsubstantive changes to the ICD–10 codes included on the PDPM code mappings and lists through a subregulatory process consisting of posting updated code mappings and lists on the PDPM website at *https://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/SNFPPS/PDPM.* Such nonsubstantive changes are limited to those specific changes that are necessary to maintain consistency with the most current ICD–10 medical code data set. On the other hand, substantive changes, or those that go beyond the intention of maintaining consistency with the most current ICD–10 medical code data set, will be proposed through notice and comment rulemaking. For instance, changes to the assignment of a code to a comorbidity list or other changes that amount to changes in policy are considered substantive changes for which we would undergo notice and comment rulemaking.

We are proposing several changes to the PDPM ICD–10 code mappings and lists. Our proposed changes are as follows:

On October 1, 2020 two ICD–10 codes representing types of sickle-cell disease; D57.42 ''Sickle-cell thalassemia beta zero without crisis'' and D57.44 ''Sickle-cell thalassemia beta plus without crisis'' took effect and were clinically mapped to the category of ''Medical Management''. However, there are more specific codes to indicate why a patient with sickle-cell disease would require SNF care, and if the patient is not in crisis, this most likely indicates that SNF care is not required. For this reason, we propose to change the assignment of D57.42 and D57.44 to ''Return to Provider''.

On October 1, 2020, three new ICD–10 codes representing types of esophageal conditions; K20.81 ''Other esophagitis with bleeding'', K20.91, ''Esophagitis, unspecified with bleeding, and K21.01 ''Gastro-esophageal reflux disease with esophagitis, with bleeding'' took effect and were clinically mapped to ''Return to Provider''. Upon review of these codes, we recognize that these codes represent these esophageal conditions with more specificity than originally considered because of the bleeding that is part of the conditions and that they would more likely be found in SNF patients. Therefore, we propose to change the assignment of K20.81, K20.91, and K21.01 to ''Medical Management'' in order to promote more accurate clinical category assignment.

In December 2020, the CDC announced several additions to the ICD–10 Classification related to COVID–19 that became effective on January 1, 2021. One such code, M35.81 ''Multisystem inflammatory syndrome'', was assigned to ''Non-Surgical Orthopedic/Musculoskeletal''. However, Multisystem inflammatory syndrome can involve more than the musculoskeletal system. It can also involve the gastrointestinal tract, heart, central nervous system, and kidneys. For this reason, we propose to change the assignment of M35.81 to ''Medical Management'' in order to promote more accurate clinical category assignment.

On October 1, 2020, three new ICD–10 codes representing types of neonatal cerebral infarction were classified as ''Return to Provider.'' These codes were P91.821 ''Neonatal cerebral infarction, right side of brain,'' P91.822, ''Neonatal cerebral infarction, left side of brain,'' and P91.823, ''Neonatal cerebral infarction, bilateral.'' While a neonate is unlikely to be a Medicare beneficiary, this diagnosis could continue to be used later in life hence placing those with this condition in the acute neurologic category. Therefore, we propose to change the assignment of P91.821, P91.822, and P91.823 to ''Acute Neurologic'' in order to promote more accurate clinical category assignment.

On April 1, 2020, U07.0, ''Vaping-related disorder,'' took effect and was classified as a ''Return to Provider'' code because at the time, ''Vaping-related disorder'' was not considered a code that would be a primary diagnosis during a SNF stay. However, upon further review, we believe that many patients who exhibit this diagnosis require steroids, empiric antibiotics and oxygen for care which could carry over to the post-acute setting. For this reason, we propose to change the assignment of U07.0 to ''Pulmonary'' classification in order to promote more accurate clinical category assignment.

In the FY 2021 proposed rule (85 FR 20939), we sought comments on additional substantive and nonsubstantive changes that commenters believed were necessary. We received three comments suggesting several changes to the ICD–10 to clinical category mappings. One of those changes was substantive, requiring notice and comment rulemaking. The

commenter suggested that the FY 2020 ICD–10 to clinical category mapping of G93.1 ''Anoxic brain damage, not elsewhere classified'' be changed to ''Acute Neurologic'' from ''Return to Provider,'' which we would consider a substantive change. Codes that result in ''Return to Provider'' are codes that cannot be used in I0020B of the MDS because item I0020B is used to establish the primary medical condition that a patient presents with during a SNF stay. Although some codes are considered ''Return to Provider'' for payment purposes, they are still used to support the care and services used for secondary and co-morbidity diagnoses. The ICD–10 code, G93.1 was initially clinically mapped to ''Return to provider'' because ''Anoxic brain damage, not elsewhere classified'' was non-specific and did not fully describe a patient's deficits and may not have been an acute condition. However, upon further review, our clinicians determined that although this may not be an acute condition, ''Anoxic brain damage, not elsewhere classified'' would still likely result in a need for SNF care and is similar to conditions such as ''Compression of the brain'', ''Cerebral edema'', and ''encephalopathy'', which are mapped into the ''Acute Neurologic'' category. Therefore, we propose to change the assignment of G93.1 ''Anoxic brain damage, not elsewhere classified'' to ''Acute Neurologic''.

We invite comments on the proposed substantive changes to the ICD–10 code mappings discussed previously, as well as comments on additional substantive and non-substantive changes that commenters believe are necessary.

C. Recalibrating the PDPM Parity Adjustment

1. Background

On October 1, 2019, we implemented the Patient Driven Payment Model (PDPM) under the SNF PPS, a new case-mix classification model that replaced the prior case-mix classification model, the Resource Utilization Groups, Version IV (RUG–IV). As discussed in the FY 2019 SNF PPS final rule (83 FR 39256), as with prior system transitions, we proposed and finalized to implement PDPM in a budget neutral manner. This means that the transition to PDPM, along with the related policies finalized in the FY 2019 SNF PPS final rule, were not intended to result in an increase or decrease in the aggregate amount of Medicare payment to SNFs. We believe ensuring parity is integral to the process of providing ''for an appropriate adjustment to account for case mix'' that is based on appropriate data in accordance with section 1888(e)(4)(G)(i) of the Act. Section V.I. of the FY 2019 SNF PPS final rule (83 FR 39255 through 39256) discusses the methodology that we used to implement PDPM in a budget neutral manner. Specifically, we multiplied each of the PDPM case-mix indexes (CMI) by an adjustment factor that was calculated by comparing total payments under RUG–IV, using FY 2017 claims and assessment data (the most recent final claims data available at the time), and what we expected total payments would be under the then proposed PDPM based on that same FY 2017 claims and assessment data. In the FY 2020 SNF PPS final rule (84 FR 38734–38735), CMS finalized an updated standardization multiplier and parity adjustment based on FY 2018 claims and assessment data. Through this comparison, and as discussed in the FY 2020 SNF PPS final rule, this analysis resulted in an adjustment factor of 1.46, by which the PDPM CMIs were multiplied so that total estimated payments under PDPM would be equal to total actual payments under RUG–IV, assuming no changes in the population, provider behavior, and coding. By multiplying the CMIs by 1.46, the CMIs were inflated by 46 percent in order to achieve budget neutrality.

A similar type of adjustment was used when we transitioned from RUG–III to RUG–IV in FY 2011. However, as discussed in the FY 2012 SNF PPS final rule (76 FR 48492 through 48500), we observed that, once actual RUG–IV utilization data became available, the actual RUG–IV utilization patterns differed significantly from those we had projected using the historical data that grounded the RUG–IV parity adjustment. As a result, in the FY 2012 SNF PPS final rule, we used actual FY 2011 RUG–IV utilization data to recalibrate the RUG–IV parity adjustment. Based on the use of FY 2011 RUG–IV utilization data, we decreased the RUG–IV parity adjustment applied to the nursing CMIs for all RUG–IV therapy groups from an adjustment factor of 61 percent to an adjustment factor of 19.84 percent (while maintaining the original 61 percent total nursing CMI increase for all non-therapy RUG–IV groups). As a result of this recalibration, FY 2012 SNF PPS rates were reduced by 12.5 percent, or $4.47 billion, in order to achieve budget neutrality under RUG–IV prospectively.

Since PDPM implementation, we have closely monitored PDPM utilization data to ascertain, among other things, if the PDPM parity adjustment provided for a budget neutral transition to this new case-mix classification model. Similar to what occurred in FY 2011 with RUG–IV implementation, we have observed significant differences between expected SNF PPS payments and case-mix utilization, based on historical data, and the actual SNF PPS payments and case-mix utilization under the PDPM, based on FY 2020 data. As a result, it would appear that rather than simply achieving parity, the FY 2020 parity adjustment may have inadvertently triggered a significant increase in overall payment levels under the SNF PPS. We believe that, based on the data from this initial phase of PDPM, a recalibration of the PDPM parity adjustment is warranted to ensure that the adjustment serves its intended purpose to make the transition between RUG–IV and PDPM budget neutral.

However, we also acknowledge that the pandemic-related PHE for COVID–19, which began during the first year of PDPM and has continued into at least part of FY 2021, has had a likely impact on SNF PPS utilization data. Further, following the methodology utilized in calculating the initial parity adjustment, we typically would use claims and assessment data for a given year to classify patients under both the current system and the prior system to compare aggregate payments between the prior system and new system and determine an appropriate adjustment factor to achieve parity. When we performed a similar recalibration of the RUG–IV parity adjustment, for example, we used data from FY 2011, the first year of RUG–IV implementation, as the basis for recalibrating the RUG–IV parity adjustment. However, in addition to the aforementioned potential issues with the FY 2020 SNF utilization data arising from the PHE for COVID–19, we are concerned that given the significant differences in both patient assessment requirements and payment incentives between RUG–IV and PDPM, using the same methodology we have used in the past to calculate a recalibrated PDPM parity adjustment could lead to a potentially inaccurate recalibration.

Therefore, given these issues, and for the reasons below, we are taking this opportunity to present some of the results of our PDPM data monitoring efforts and a potential recalibration methodology intended to address the issues presented above. First, it is important to provide transparency on the observed impacts of PDPM implementation, as we do believe there have been significant changes observed in SNF utilization that are tied strictly to PDPM and not the PHE for COVID–19. Second, we wish to make clear why we believe that the typical methodology for recalibrating the parity adjustment

may not provide an accurate recalibration under PDPM. Finally, we view this as an opportunity to seek comment on a path forward for recalibrating the PDPM parity adjustment to ensure that PDPM is implemented in a budget neutral manner, as intended.

2. FY 2020 Changes in SNF Case-Mix Utilization

FY 2020 was a year of significant change under the SNF PPS. In addition to implementing PDPM, a national PHE for COVID–19 was declared. With the announcement of the PHE for COVID–19, we also announced a number of waivers which impacted SNF operations and the population of Medicare beneficiaries who were able to access the Part A SNF benefit. Most notably, under authority granted us by section 1812(f) of the Act, we issued a waiver of section 1861(i) of the Act, specifically the requirement that in order for a SNF stay to be covered by Medicare, a beneficiary must have a prior inpatient hospital stay of not less than 3 consecutive days before being admitted to the Part A SNF stay. Additionally, this waiver also allowed certain beneficiaries renewed SNF coverage without first having to start a new benefit period. The section 1812(f) waiver, particularly the component which permits beneficiaries to access the Part A SNF benefit without a prior hospitalization, allowed beneficiaries who would not typically be able to access the Part A SNF benefit to receive a Part A covered SNF stay (for example, long term care nursing home patients without any prior hospitalization). A key aspect of our methodology for recalibrating the PDPM parity adjustment involves parsing out the impact of these waivers and the different population of beneficiaries that had access to the SNF benefit as result of these waivers from the population of beneficiaries that would have been admitted to SNFs subsequent to PDPM implementation without these waivers, as well as differences in the type of care these patients received. We would note that while the PHE for COVID–19 clearly had impacts on nursing home care protocols and many other aspects of SNF operations, the relevant issue for pursuing a recalibration of the PDPM parity adjustment is whether or not these changes caused the SNF case-mix distribution to be distinctly different from what it would have been were it not for the PHE for COVID–19. In other words, while different people were able to access the Part A SNF benefit than would typically be able to do so, the issue is whether or not the relative percentage of beneficiaries in each PDPM group is different than what those percentages would have been were it not for the PHE for COVID–19 and related waivers. We solicit comments on whether stakeholders believe that the PHE for COVID–19 impacted on the distribution of patient case-mix.

To understand the potential impact of the PHE for COVID–19 on SNF utilization data, we can begin by understanding the overall utilization of the waivers and the overall frequency of COVID–19 diagnoses among the SNF population. In FY 2020, only approximately 9.8 percent of SNF stays included a COVID–19 ICD–10 diagnosis code (either as a primary or secondary diagnosis), while 15.6 percent of SNF stays utilized a section 1812(f) waiver (with the majority of these cases using the prior hospitalization waiver), as identified by the presence of a ''DR'' condition code on the SNF claim. As compared to prior years, when approximately 98 percent of SNF beneficiaries had a qualifying prior hospital stay, approximately 87 percent of SNF beneficiaries had a qualifying prior hospitalization in FY 2020. These general statistics are important, as they highlight that while the PHE for COVID–19 certainly impacted many aspects of nursing home operations, the overwhelming majority of SNF beneficiaries entered into Part A SNF stays in FY 2020 as they would have in any other year; that is, without using a PHE-related waiver, with a prior hospitalization, and without a COVID–19 diagnosis. In fact, as we discuss further below, even when removing those using a PHE-related waiver and those with a COVID–19 diagnosis from our dataset, the observed inadvertent increase in SNF payments since PDPM was implemented is approximately the same. This would seem to imply that this ''new'' population of SNF beneficiaries (that is, COVID–19 patients and those using a section 1812(f) waiver) does not appear to be the cause of the increase in SNF payments after implementation of PDPM, since we would expect a much greater impact on the calculation of the necessary recalibration from removing this population from our analysis if that were the case.

Moreover, we do believe that there is clear evidence that PDPM alone is impacting certain aspects of SNF patient classification and care provision. For example, through FY 2019, the average number of therapy minutes SNF patients received per day was approximately 91 minutes. Beginning almost immediately with PDPM implementation (and well before the onset of the pandemic), the average number of therapy minutes SNF patients received per day dropped to approximately 62, a decrease of over 30 percent. Given both the immediacy and ubiquity of this change in the SNF data, without any concurrent change in the SNF population, it is clear that this overall decrease in the amount of therapy services provided to SNF patients is a result of PDPM implementation and not other factors. A number of media articles further corroborated this finding, which identified significant changes in therapy staffing and care directives at the outset of PDPM. Similarly, we also observed an increase in non-individualized modes of therapy provision beginning with PDPM implementation. Specifically, while the percentage of SNF stays which included concurrent or group therapy was approximately 1 percent for each of these therapy modes prior to FY 2020, these numbers rose to approximately 32 percent and 29 percent, respectively, beginning in the first month of PDPM implementation. Coincidentally, these numbers then dropped to 8 percent and 4 percent, respectively, beginning in April 2020, close to when the PHE for COVID–19 was declared (highlighting at least one impact of the PHE for COVID–19 on SNF care provision and utilization). We also note that while these findings (increases in concurrent and group therapy utilization) were anticipated prior to PDPM implementation based on comments on the FY 2019 and FY 2020 SNF PPS proposed rules, we maintain the belief that the unique characteristics and goals of each SNF patient should drive patient care decisions. As we stated in the FY 2020 SNF PPS final rule (84 FR 38748), we believe that financial motives should not override the clinical judgment of a therapist or therapy assistant or pressure a therapist or therapy assistant to provide less than appropriate therapy. We would also note that, despite these changes in therapy provision, we did not identify any significant changes in health outcomes for SNF patients. For example, we observed no changes in the percentage of stays with falls with major injury, the percentage of stays ending with Stage 2–4 or unstageable pressure ulcers or deep tissue injury, the percentage of stays readmitted to an inpatient hospital setting within 30 days of SNF discharge, or other similar metrics. We will continue to monitor these and other metrics to identify any adverse trends that may have been caused by changes in care patterns that

accompanied the implementation of PDPM.

These changes in therapy provision highlight the reasons we believe that the typical methodology for recalibrating a parity adjustment would not be appropriate in the context of PDPM. As discussed previously in this proposed rule and in the FY 2012 SNF PPS final rule (76 FR 26371), we would typically utilize claims and assessment data from a given period under the new payment system, classify patients under both the current and prior payment model using this same set of data, compare aggregate payments under each payment model, and calculate an appropriate adjustment factor to achieve budget neutrality. However, given the significant changes in therapy provision since PDPM implementation, we found that using patient assessment data collected under PDPM (for example, FY 2020 data) would lead to a drastic underestimation of RUG–IV case mix for purposes of determining what aggregate payments would have been under RUG–IV for the same period. In other words, given the significant reduction in the overall amount of therapy provided to SNF patients since PDPM implementation, as well as changes in the way that the therapy is provided (for example, increases in group and concurrent therapy), classifying SNF patients into RUG–IV payment groups using data collected under PDPM would lead to a RUG–IV case-mix distribution that contrasts significantly with historical trends under RUG–IV. This finding is precisely why we do not believe that the typical methodology for recalibrating the PDPM parity adjustment would result in an accurate calculation of the revised parity adjustment factor and may lead to an overcorrection. We invite comments on the information presented above, as well as on the potential impact of using the reported FY 2020 patient assessment data from the MDS to reclassify SNF beneficiaries under RUG–IV, consistent with the same type of recalibration methodology we have used after prior system transitions. Below, we discuss the methodology we are considering for recalibrating the PDPM parity adjustment, which we believe accounts for this change in therapy provision.

3. Methodology for Recalibrating the PDPM Parity Adjustment

As discussed above, we have identified an inadvertent increase in SNF spending since implementing PDPM. As in the past, identifying the scope and magnitude of this type of inadvertent increase begins with looking at the type of case-mix distribution that was expected under the new case-mix system and the actual case-mix distribution that occurs under the new case-mix system. In the FY 2012 SNF PPS proposed rule (76 FR 26371), we were able to provide a table which listed each of the RUG–IV payment groups with the projected and actual percentage of SNF days of service associated with each group. Due to the number of possible payment groups under PDPM, this type of table is not possible. However, Table 23 provides the average PDPM case-mix index expected for each of the PDPM rate components based on data from FY 2019. This average is calculated for each component by summing the expected PDPM case-mix index for each day of service and then dividing this number by the total number of FY 2019 days of service. Table 23 also provides the actual average PDPM case-mix index for each of these components in two different ways. First, we used FY 2020 data for the full SNF population and, following the same methodology described above to determine the expected average PDPM case-mix index, we summed the case-mix index for each day of service in FY 2020 and then divided this by the total number of FY 2020 days of service. Second, we used FY 2020 data for the SNF population excluding those SNF stays where either the patient was diagnosed with COVID–19 or the stay utilized a PHE for COVID–19 related waiver (for example, the waiver issued under authority granted by section 1812(f) of the Act to allow Part A coverage of a SNF stay without a qualifying prior hospital stay), as identified by the presence of a ''DR'' condition code on the associated SNF claim. We evaluated the average CMI using this subset of the SNF population as we believe it would provide a way to identify the effect of the PHE for COVID–19 on FY 2020 case mix and the recalibration calculation if we were to use FY 2020 data collected during the PHE for COVID–19. The results of this analysis are provided in Table 23.

TABLE 23—AVERAGE CASE-MIX INDEX, EXPECTED AND ACTUAL, BY COMPONENT

Component	Expected CMI (FY 2019 Estimate)	Actual CMI (FY 2020)	Actual CMI (FY 2020 without DR or COVID)
	Average CMI	Average CMI	Average CMI
PT	1.53	1.50	1.52
OT	1.52	1.51	1.52
SLP	1.39	1.71	1.67
Nursing	1.43	1.67	1.62
NTA	1.14	1.20	1.21

According to this analysis, while we observed slight decreases in the average CMI for the PT and OT rate components for both the full and subset FY 2020 populations as compared to what was expected, we observed significant increases in the average CMI for the SLP, Nursing, and NTA components for both the full and subset FY 2020 populations as compared to what was expected, with increases of 22.6 percent, 16.8 percent, and 5.6 percent, respectively, for the full FY 2020 SNF population. We believe these significant increases in the average case-mix for these components is primarily responsible for the inadvertent increase in spending under PDPM. Further, given that we observe similar increases in the average CMI for these components even when using the subset of the FY 2020 SNF population that excludes those patients diagnosed with COVID–19 or who used a PHE-related waiver, we believe that these increases in average case-mix for these components are the result of PDPM and not the PHE for COVID–19. We invite comments on this approach and the extent to which commenters believe that the PHE for COVID–19 may have impacted on the PDPM case-mix distribution in ways not captured in Table 23 or in the discussion provided here.

Our basic methodology for recalibrating the parity adjustment has

been to compare total payments under the new case-mix model with what total payments would have been under the prior case-mix model, were the new model not implemented. In the context of the PDPM, this means comparing total FY 2020 payments under PDPM to what FY 2020 payments would have been under RUG–IV if PDPM were not implemented. In order to calculate the actual total payments under PDPM for this proposed rule, we used data reported on FY 2020 claims. Specifically, we used the Health Insurance Prospective Payment System (HIPPS) code on the SNF claim to identify the patient's case-mix assignment and associated CMIs, utilization days on the claim to calculate stay payments and to compute the variable per diem adjustment, the presence of an HIV diagnosis on the claim to account for the PDPM AIDS add-on, and finally, we accounted for the provider's urban or rural status. As with the analysis that led to Table 23, we calculated total payments both for the full SNF population in FY 2020, as well as the subset of that population removing those with a COVID–19 diagnosis and those using a PHE-related waiver.

In order to calculate expected total payments under RUG–IV, in light of the discussion above (which describes why we believe it would not be appropriate simply to reclassify SNF patients under RUG–IV using the information reported in FY 2020), we used the percentage of stays in each RUG–IV group in FY 2019 and multiplied these percentages by the total number of FY 2020 days of service. We then multiplied the number of days for each RUG–IV group by the RUG–IV per diem rate, which we obtained by inflating the FY 2019 SNF PPS RUG–IV rates by the FY 2020 market basket update factor, as we would have were it not for the implementation of PDPM. The total payments under RUG–IV also account for the difference in how the AIDS add-on is calculated under RUG–IV, as compared to PDPM, and similarly accounts for a provider's FY 2020 urban or rural status.

We believe that this methodology provides a more accurate representation of what RUG–IV payments would have been in FY 2020 were it not for the change in payment incentives and care provision precipitated by PDPM implementation, than using data reported under PDPM to reclassify these patients under RUG–IV. In particular, given the reduction in therapy utilization under PDPM, as compared to RUG–IV, using the therapy utilization data reported under PDPM to reclassify SNF patients back into RUG–IV groups would produce a case-mix distribution that would be significantly different from the RUG–IV case-mix distribution we would have expected were it not for PDPM implementation. Since the reduction in therapy would lead to a reduction in the RUG–IV case-mix assignments (for example, Ultra-High and Very-High Rehabilitation assignments are not nearly as prevalent using PDPM-reported data as they are using data that existed prior to PDPM), this would lead to an underestimation of what RUG–IV payments would have been in FY 2020. This, in turn, would lead to an overcorrection in recalibrating the parity adjustment due to the low estimated total RUG–IV payments. Additionally, given the significant changes in the patient assessment schedule, specifically the removal of the Change of Therapy Other Medicare Required Assessment, we cannot know if the patient would continue to remain classified in the RUG–IV group into which the patient classified on the 5-day assessment beyond that assessment window. In other words, without having an interim assessment between the 5-day assessment and the patient's discharge from the facility, we would be unable to determine if the RUG–IV group into which the patient classified on the 5-day assessment changed during the stay or if the patient continued to receive an amount of therapy services consistent with this initial RUG–IV classification. As a result, using reported data under PDPM could lead to a reclassification of patients under RUG–IV that is not consistent with how patients would have been classified under RUG–IV if PDPM had not been implemented. As such, we believe that using the FY 2019 RUG–IV case-mix distribution as a proxy for what the RUG–IV case-mix distribution would have been in FY 2020 were it not for PDPM implementation, provides a more accurate calculation of what total RUG–IV payments would have been during FY 2020 absent PDPM implementation.

The result of these analyses was that we identified a 5.3 percent increase in aggregate spending under PDPM as compared to expected total payments under RUG–IV for FY 2020 when considering the full SNF population, and a 5.0 percent increase in aggregate spending under PDPM for FY 2020 when considering the subset population. Although these results are similar, in light of the potential differences in the PDPM case-mix distribution which may have been precipitated by the admission of patients diagnosed with COVID–19 and patients whose stays utilized a PHE-related waiver, we believe it would be more appropriate to pursue a recalibration using the subset population. We invite comments on our methodology, particularly on the use of the FY 2019 RUG–IV case-mix distribution to calculate expected FY 2020 SNF payments if PDPM were not implemented and on using the subset FY 2020 SNF population which excludes patients diagnosed with COVID–19 and those using a PHE-related waiver in our recalibration calculation rather than the full FY 2020 SNF population.

Based on the above discussion and analysis, we have described above a potential path towards a recalibration of the PDPM parity adjustment using a subset of the full FY 2020 SNF data set. Since the initial increase applied to the PDPM CMIs to achieve budget neutrality applied equally across all case-mix adjusted components, we believe it would be appropriate, in the event an adjustment is made, to adjust the CMIs across all such components in equal measure. Using the methodology described above, the resultant PDPM parity adjustment factor would be lowered from 46 percent to 37 percent for each of the PDPM case-mix adjusted components. If this were applied for FY 2022, we estimate that this methodology would result in a reduction in SNF spending of 5.0 percent, or approximately $1.7 billion.

Tables 24 and 25 set forth what the FY 2022 PDPM CMIs and case-mix adjusted rates would be if we applied the recalibration methodology described above in FY 2022.

TABLE 24—RECALIBRATED PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.44	$90.49	1.40	$81.89	0.64	$15.01	ES3	3.82	$418.48	3.05	$252.05
B	1.60	100.54	1.53	89.49	1.71	40.12	ES2	2.89	316.60	2.38	196.68
C	1.77	111.23	1.59	93.00	2.51	58.88	ES1	2.76	302.36	1.73	142.97
D	1.81	113.74	1.44	84.23	1.37	32.14	HDE2	2.26	247.58	1.25	103.30

TABLE 24—RECALIBRATED PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—URBAN—Continued

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
E	1.34	84.21	1.33	77.79	2.2	51.61	HDE1	1.87	204.86	0.9	74.38
F	1.52	95.52	1.51	88.32	2.80	65.69	HBC2	2.11	231.15	0.68	56.20
G	1.57	98.66	1.54	90.07	1.92	45.04	HBC1	1.75	191.71		
H	1.09	68.50	1.08	63.17	2.69	63.11	LDE2	1.96	214.72		
I	1.06	66.61	1.11	64.92	3.32	77.89	LDE1	1.63	178.57		
J	1.34	84.21	1.36	79.55	2.81	65.92	LBC2	1.62	177.47		
K	1.43	89.86	1.45	84.81	3.48	81.64	LBC1	1.35	147.89		
L	1.03	64.73	1.04	60.83	3.96	92.90	CDE2	1.76	192.81		
M	1.20	75.41	1.22	71.36			CDE1	1.52	166.52		
N	1.39	87.35	1.41	82.47			CBC2	1.46	159.94		
O	1.46	91.75	1.46	85.40			CA2	1.03	112.84		
P	1.02	64.10	1.03	60.24			CBC1	1.26	138.03		
Q							CA1	0.88	96.40		
R							BAB2	0.98	107.36		
S							BAB1	0.93	101.88		
T							PDE2	1.48	162.13		
U							PDE1	1.38	151.18		
V							PBC2	1.15	125.98		
W							PA2	0.67	73.40		
X							PBC1	1.06	116.12		
Y							PA1	0.62	67.92		

TABLE 25: RECALIBRATED PDPM CASE-MIX ADJUSTED FEDERAL RATES AND ASSOCIATED INDEXES—RURAL

PDPM group	PT CMI	PT rate	OT CMI	OT rate	SLP CMI	SLP rate	Nursing CMG	Nursing CMI	Nursing rate	NTA CMI	NTA rate
A	1.44	$103.15	1.40	$92.11	0.64	$18.92	ES3	3.82	$399.80	3.05	$240.83
B	1.60	114.61	1.53	100.66	1.71	50.55	ES2	2.89	302.47	2.38	187.92
C	1.77	126.79	1.59	104.61	2.51	74.20	ES1	2.76	288.86	1.73	136.60
D	1.81	129.65	1.44	94.74	1.37	40.50	HDE2	2.26	236.53	1.25	98.70
E	1.34	95.98	1.33	87.50	2.2	65.03	HDE1	1.87	195.71	0.9	71.06
F	1.52	108.88	1.51	99.34	2.8	82.77	HBC2	2.11	220.83	0.68	53.69
G	1.57	112.46	1.54	101.32	1.92	56.76	HBC1	1.75	183.16		
H	1.09	78.08	1.08	71.05	2.69	79.52	LDE2	1.96	205.13		
I	1.06	75.93	1.11	73.03	3.32	98.14	LDE1	1.63	170.60		
J	1.34	95.98	1.36	89.47	2.81	83.06	LBC2	1.62	169.55		
K	1.43	102.43	1.45	95.40	3.48	102.87	LBC1	1.35	141.29		
L	1.03	73.78	1.04	68.42	3.96	117.06	CDE2	1.76	184.20		
M	1.20	85.96	1.22	80.26			CDE1	1.52	159.08		
N	1.39	99.57	1.41	92.76			CBC2	1.46	152.80		
O	1.46	104.58	1.46	96.05			CA2	1.03	107.80		
P	1.02	73.06	1.03	67.76			CBC1	1.26	131.87		
Q							CA1	0.88	92.10		
R							BAB2	0.98	102.57		
S							BAB1	0.93	97.33		
T							PDE2	1.48	154.90		
U							PDE1	1.38	144.43		
V							PBC2	1.15	120.36		
W							PA2	0.67	70.12		
X							PBC1	1.06	110.94		
Y							PA1	0.62	64.89		

We invite comments on the methodology described in this section of the proposed rule for recalibrating the PDPM parity adjustment, as well as the findings of our analysis described throughout this section. To assist commenters in providing comments on this issue, we have also posted a file on the CMS website, at *https://www.cms.gov/snfpps,* which provides the FY 2019 RUG–IV case-mix distribution and calculation of total payments under RUG–IV, as well as PDPM case-mix utilization data at the case-mix group and component level to demonstrate the calculation of total payments under PDPM. As we noted in the FY 2012 SNF PPS final rule (76 FR 48493), we believe it is imperative that we act in a well-considered but expedient manner once excess payments are identified, as we did in FY 2012.

However, in the event we confirm the finding that the current implementation of PDPM is not budget neutral and that a recalibration is appropriate, despite the importance of ensuring that PDPM is budget neutral going forward, we acknowledge the possibility that applying such a significant reduction in payments in a single year and without time to prepare for the reduction in revenue could create a financial burden for providers. In light of this possibility, we are also considering a number of potential mitigation strategies that would help to ease the transition to prospective budget neutrality in the event an adjustment is finalized. These strategies fall into two broad categories: Delayed implementation; and phased implementation.

With regard to a delayed implementation strategy, this would mean that we would implement the reduction in payment, or some portion of the reduction in payment if combined with a phased implementation approach described below, in a later year than the year in which the reduction is finalized. For example, considering the 5 percent reduction discussed above, if this reduction was finalized in FY 2022 with

a 1 year delayed implementation, this would mean that the full 5 percent reduction would be prospectively applied to the PDPM CMIs in FY 2023. If the reduction was finalized in FY 2022 with a 2 year delayed implementation, then the reduction in the PDPM CMIs would be applied prospectively beginning in FY 2024. This type of strategy, on its own, does not serve to mitigate the overall amount of the reduction in a single year, but rather serves to provide facilities with time to prepare for the impending reduction in payments. We solicit comments on whether stakeholders believe that, in the event we finalize the parity adjustment recalibration, we should finalize this recalibration with a delayed implementation. Additionally, to the extent that stakeholders believe that a delayed implementation would be warranted, we solicit comments on the appropriate length of the delay.

With regard to a phased implementation strategy, this would mean that the amount of the reduction would be spread out over some number of years. Such an approach helps to mitigate the impact of the reduction in payments by applying only a portion of the reduction in a given year. For example, if we were to use a 2-year phased implementation approach to the 5 percent reduction discussed above, this would mean that the PDPM CMIs would be reduced by 2.5 percent in the first year of implementation and then reduced by the remaining 2.5 percent in the second and final year of implementation. So, for example, if this adjustment was finalized for FY 2022, then the PDPM CMIs would be reduced by 2.5 percent in FY 2022 and then reduced by an additional 2.5 percent in FY 2023. We note that the number of years for a phased implementation approach could be as little as 2 years but as long as necessary to appropriately mitigate the yearly impact of the reduction. For example, we could implement a 5-year phased approach for this reduction, which would apply a one percent reduction to the PDPM CMIs each year for 5 years. We solicit comments on the need for a phased implementation approach to recalibrating the PDPM parity adjustment, as well as on the appropriate length of such an approach.

We would, finally, note that these mitigation strategies may be used in combination with each other. For example, we could finalize a 2 year phased approach with a 1 year delayed implementation. Using FY 2022 as the hypothetical year in which such an approach could be finalized, this would mean that there would be no reduction to the PDPM CMIs in FY 2022, a 2.5 percent reduction to the PDPM CMIs in FY 2023 and then a 2.5 percent reduction in the PDPM CMIs in FY 2024. We solicit comments on the possibility of combining these approaches and what stakeholders believe would be appropriate, using these approaches, to appropriately mitigate the impact of the reduction in SNF PPS payments.

We note that in any of these options, the adjustment would be applied prospectively, and the case mix indexes would not be adjusted to account for deviations from budget neutrality in years before the payment adjustments were implemented.

We are considering these approaches as they may be warranted to mitigate potential negative impacts on providers resulting from implementation of such a reduction in the SNF PPS rates entirely within a single year in the event we determine that recalibrating the parity adjustment is necessary to achieve budget neutrality. However, we believe that these alternatives would continue to reimburse in amounts that significantly exceed our intended policy in excess of the rates that would have been paid had we maintained the prior payment classification system rather than in a budget neutral manner as intended, and as we stated above, we believe it is imperative that we act in a well-considered but appropriately expedient manner once excess payments are identified. In addition, as we move forward with programs designed to enhance and restructure our post-acute care payment systems, we believe that payments under the SNF PPS should be established at their intended and most appropriate levels as quickly as possible. Moreover, stabilizing the baseline is a necessary first step toward properly implementing and maintaining the integrity of the PDPM classification methodology and the SNF PPS as a whole as discussed above. We invite comments on the mitigation strategies described above for mitigating the impact of recalibrating the PDPM parity adjustment in the event we finalize a recalibration.

VI. Skilled Nursing Facility (SNF) Quality Reporting Program (QRP)

A. Background and Statutory Authority

The Skilled Nursing Facility Quality Reporting Program (SNF QRP) is authorized by section 1888(e)(6) of the Act, and it applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(e)(6)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual market basket percentage update described in section 1888(e)(5)(B)(i) of the Act applicable to a SNF for a fiscal year, after application of section 1888(e)(5)(B)(ii) of the Act (the multifactor productivity (MFP) adjustment) and section 1888(e)(5)(B)(iii) of the Act, in the case of a SNF that does not submit data in accordance with sections 1888(e)(6)(B)(i)(II) and (III) of the Act for that fiscal year. For more information on the requirements we have adopted for the SNF QRP, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46427 through 46429), FY 2017 SNF PPS final rule (81 FR 52009 through 52010), FY 2018 SNF PPS final rule (82 FR 36566 through 36605), FY 2019 SNF PPS final rule (83 FR 39162 through 39272), and FY 2020 SNF PPS final rule (84 FR 38728 through 38820).

B. General Considerations Used for the Selection of Measures for the SNF QRP

For a detailed discussion of the considerations we use for the selection of SNF QRP quality, resource use, or other measures, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46429 through 46431).

1. Quality Measures Currently Adopted for the FY 2022 SNF QRP

The SNF QRP currently has 13 measures for the FY 2022 SNF QRP, which are outlined in Table 26. For a discussion of the factors used to evaluate whether a measure should be removed from the SNF QRP, we refer readers to 42 CFR 413.360(b)(3).

TABLE 26—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2022 SNF QRP

Short name	Measure name & data source
Resident Assessment Instrument Minimum Data Set (Assessment-Based)	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.

TABLE 26—QUALITY MEASURES CURRENTLY ADOPTED FOR THE FY 2022 SNF QRP—Continued

Short name	Measure name & data source
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay) (NQF #0674).
Application of Functional Assessment/Care Plan.	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (NQF #2631).
Change in Mobility Score	Application of IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (NQF #2634).
Discharge Mobility Score	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (NQF #2636).
Change in Self-Care Score	Application of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633).
Discharge Self-Care Score	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (NQF #2635).
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues—Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
TOH–Provider*	Transfer of Health Information to the Provider Post-Acute Care (PAC).
TOH–Patient*	Transfer of Health Information to the Patient Post-Acute Care (PAC).
Claims-Based	
MSPB SNF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Skilled Nursing Facility (SNF) Quality Reporting Program (QRP) (NQF #3481).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility (SNF) Quality Reporting Program (QRP).

*In response to the public health emergency (PHE) for the Coronavirus Disease 2019 (COVID–19), CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for collection and reporting of the Transfer of Health Information measures for at least two full fiscal years after the end of the PHE.

C. SNF QRP Quality Measure Proposals Beginning With the FY 2023 SNF QRP

Section 1899B(h)(1) of the Act permits the Secretary to remove, suspend, or add quality measures or resource use or other measures described in sections 1899B(c)(1) and (d)(1) of the Act, respectively, so long as the Secretary publishes in the **Federal Register** (with a notice and comment period) a justification for such removal, suspension or addition. Section 1899B(a)(1)(B) of the Act requires that all of the data that must be reported in accordance with section 1899B(a)(1)(A) of the Act (including resource use or other measure data under section 1899B(d)(1)) be standardized and interoperable to allow for the exchange of the information among post-acute care (PAC) providers and other providers and the use by such providers of such data to enable access to longitudinal information and to facilitate coordinated care.

We propose to adopt two new measures for the SNF QRP beginning with the FY 2023 SNF QRP: The SNF Healthcare-Associated Infections Requiring Hospitalization measure (SNF HAI) and the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP)[4] measure as an ''other measure'' under section 1899B(d)(1) of the Act. The SNF HAI measure is an outcome measure. The data used to report the SNF HAI measure are standardized and interoperable and would allow providers to exchange this data and compare outcomes across the care continuum and PAC settings. Clinical data captured in every clinical setting informs a resident's current medical care plan, facilitates coordinated care, and improves Medicare beneficiary outcomes. We plan to develop HAI measures in other PAC settings, such as the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program and the Long-Term Care Hospital (LTCH) Quality Reporting Program. The proposed measure supports the CMS Meaningful Measures Initiative through the Making Care Safer by Reducing Harm Caused in the Delivery of Care domain. We have previously solicited feedback on the SNF HAI measure as a future measure for the SNF QRP and received several comments of support as well as a few comments recommending suggestions (84 FR 38765). The measure is described in more detail below.

We are proposing the COVID–19 Vaccination Coverage among HCP measure as an ''other'' measure under section 1899B(d)(1) of the Act beginning with the FY 2023 SNF QRP. In accordance with section 1899B(a)(1)(B) of the Act, the data used to calculate this measure are standardized and interoperable. The proposed measure supports the Meaningful Measures domain of Promote Effective Prevention and Treatment of Chronic Disease. We identified the measure concept as a priority in response to the current public health crisis. This process measure was developed with the Centers for Disease Control and Prevention (CDC) to track COVID–19 vaccination coverage among HCP in the SNF setting. This measure is described in more detail below.

In addition, we propose to update the denominator for one measure, the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure to exclude residents discharged home under the care of an organized home health service or hospice.

1. Proposed Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAI) Requiring Hospitalization Quality Measure Beginning With the FY 2023 SNF QRP

a. Background

Monitoring the occurrence of HAIs among SNF residents can provide valuable information about a SNF's quality of care. Although HAIs are not considered ''never events'', or serious adverse errors in the provision of health care services that should never occur,

[4] The measure steward changed the name of the measure from SARS–CoV–2 Vaccination Coverage among Healthcare Personnel to COVID–19 Vaccination Coverage among Healthcare Personnel. There were no changes to the measure itself, other than the name change.

most are preventable as they are often the result of poor processes and structures of care.[5] Evidence suggests there is a wide variation in HAI rates among SNF providers. An analysis of FY 2018 SNF claims indicates a performance gap in HAI rates across SNFs. Among the 14,347 SNFs included in the sample for the analysis, risk-adjusted measure scores ranged from a minimum of 2.19 percent to a maximum of 19.83 percent. Further, a 2014 report from the Office of the Inspector General (OIG) estimated that one in four adverse events among SNF residents are due to HAIs, and more than half of all HAIs are potentially preventable.[6] Typically, HAIs result from inadequate patient management following a medical intervention, such as surgery or device implementation, or poor adherence to protocol and antibiotic stewardship guidelines.[7] [8] [9] Several provider characteristics are also related to HAIs including staffing levels (for example, high turnover, low staff-to-resident ratios, etc.), facility structure characteristics (for example, national chain membership, high occupancy rates, etc.), and adoption or lack thereof of infection surveillance and prevention policies.[10] [11] [12] [13] [14] [15] Inadequate prevention and treatment of HAIs is likely to result in poor health care outcomes for residents and wasteful resource use. For example, HAIs are associated with longer lengths of stay, use of higher-intensity care (for example, critical care services and hospital readmissions), increased mortality, and high health care costs.[16,17,18,19] Monitoring SNF HAI rates would provide information about each facility's adeptness in infection prevention and management.

Addressing HAIs in SNFs is particularly important as several factors place SNF residents at high risk for infection, including increased age, cognitive and functional decline, use of indwelling devices, frequent care transitions, and close contact with other resident and healthcare workers.[20] [21] Furthermore, in SNFs, COVID–19 has a disproportionate impact on racial and ethnic minorities as well as people living with disabilities.[22] [23] Emerging COVID–19 studies reveal higher patient spread due to poor infection control, staff rotations between multiple SNFs, and poor patient COVID–19 screenings.[24] [25] An analysis comparing SNF HAI rates using FY 2019 data with the currently reported rates of COVID–19 in SNFs found that nursing homes with higher HAI rates in FY 2019 also have a higher number of COVID–19 cases.[26] This analysis was presented to the PAC–LTC MAP Workgroup at the January 11th meeting (*http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94559,* slide 134). We believe this finding supports a relationship not only between this measure and overall HAI prevention and control in SNFs, but also in predicting those SNFs more likely to have higher rates of infection in future pandemics. Several interventions may reduce HAI rates among SNFs, thus improving quality of care. These interventions include the adoption of infection surveillance and prevention policies, safety procedures, antibiotic stewardship, and staff education and training

[5] CMS. (2006). Eliminating Serious Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

[6] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

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[15] Travers, J.L., Stone, P.W., Bjarnadottir, R.I., Pogorzelska-Maziarz, M., Castle, N.G., & Herzig, C.T. (2016). Factors associated with resident influenza vaccination in a national sample of nursing homes. American Journal of Infection Control, 44(9), 1055–1057. *http://dx.doi.org/10.1016/j.ajic.2016.01.019.*

[16] CMS. (2006). Eliminating Serious Preventable, and Costly Medical Errors—Never Events. Retrieved from *https://www.cms.gov/newsroom/fact-sheets/eliminating-serious-preventable-and-costly-medical-errors-never-events.*

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[26] The CMS COVID–19 Nursing Home Dataset used in this analysis was not limited to just the SNF, but applied to the entire nursing home. The study population of the analysis includes Medicare-certified nursing homes providing SNF care.

programs.[27] [28] [29] [30] [31] [32] [33] Additionally, infection prevention and control programs with core components in education, monitoring, and feedback on infection rates from surveillance programs or feedback on infection control practices from audits have been found to be successful interventions for reducing HAIs.[34] The effectiveness of these interventions suggests improvement of HAI rates among SNF residents is possible through modifying provider-led processes and interventions.

The proposed SNF HAI measure uses Medicare fee-for-service (FFS) claims data to estimate the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization. Unlike other HAI measures that target specific infections, this measure would target all HAIs serious enough to require admission to an acute care hospital. Given the current COVID–19 public health emergency, we believe this measure would promote patient safety and increase the transparency of quality of care in the SNF setting. This measure also compares SNFs to their peers to statistically separate those that perform better than or worse than each other in infection prevention and management. We believe peer comparison would encourage SNFs to improve the quality of care they deliver.

b. Stakeholder and Technical Expert Panel (TEP) Input

In our development and specification of this measure, we employed a transparent process in which we sought input from stakeholders and national experts and engaged in a process that allowed for pre-rulemaking input, in accordance with section 1890A of the Act.

To meet this requirement, we provided the following opportunities for stakeholder input. Our measure development contractor for the SNF HAI measure convened a Technical Expert Panel (TEP) on May 9, 2019 to obtain expert input on the development of an HAI measure for use in the SNF QRP. The TEP consisted of stakeholders with a diverse range of expertise, including SNF and PAC subject matter knowledge, clinical and infectious disease expertise, patient and family perspectives, and measure development experience. The TEP supported the proposed measure concept and provided substantive input regarding the measure's specifications. Recommendations provided by the TEP included refining the measure's operational definition, exclusion criteria, and HAI ICD–10 diagnosis code list, among other considerations. All recommendations from the TEP were taken into consideration and applied appropriately where feasible. A summary of the TEP proceedings titled SNF HAI Final TEP Report is available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

Following the TEP, our measure development contractor released draft quality measure specifications for public comment on the SNF HAI measure. Stakeholder feedback was solicited on the proposed measure by requesting comment on the CMS Measures Management System Blueprint site. The comment submission period was from September 14, 2020 to October 14, 2020. Comments on the measure varied. Many commenters supported the idea of adopting an HAI measure to improve prevention efforts; however, commenters also offered criticisms about the measure's specifications and implementation. The summary report of the September 14 to October 14, 2020 public comment period titled *SNF HAI Public Comment Summary Report* is available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

c. Measure Applications Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures under Consideration (MUC) List, that the Secretary is considering adopting through the Federal rulemaking process for use in Medicare programs. This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list.

We included the SNF HAI measure under the SNF QRP Program in the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List).[35] The National Quality Forum (NQF)-convened Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care (PAC–LTC) workgroup met virtually on January 11, 2021 and provided input on the proposed measure. The MAP offered conditional support of the SNF HAI measure for rulemaking contingent upon NQF endorsement, noting that the measure adds value to the SNF QRP by presenting one overall measurement of all HAIs acquired during SNF care that result in hospitalizations, information that is not currently available. The MAP recognized that the proposed measure is intended to reflect global infection control for a facility, and may encourage SNFs to access processes and perform interventions to reduce adverse events among SNF residents that are due to HAIs. The MAP Rural Health

[27] Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from *https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf.*

[28] Beganovic, M., & Laplante, K. (2018). Communicating with Facility Leadership; Metrics for Successful Antimicrobial Stewardship Programs (Asp) in Acute Care and Long-Term Care Facilities. Rhode Island medical journal (2013), 101(5) (2018), 45–49.

[29] Crnich, C.J., Jump, R., Trautner, B., Sloane, P.D., & Mody, L. (2015). Optimizing antibiotic stewardship in nursing homes: A narrative review and recommendations for improvement. Drugs & Aging, 32(9), 699–716. *http://dx.doi.org/10.1007/s40266-015-0292-7.*

[30] Freeman-Jobson, J.H., Rogers, J.L., & Ward-Smith, P. (2016). Effect of an education presentation on the knowledge and awareness of urinary tract infection among non-licensed and licensed health care workers in long-term care facilities. Urologic Nursing, 36(2), 67–71. *http://dx.doi.org/10.7257/1053-816X.2016.36.2.67* Crnich, C.J., Jump, R., Trautner, B., Sloane, P.D., & Mody, L. (2015). Optimizing antibiotic stewardship in nursing homes: A narrative review and recommendations for improvement. Drugs & Aging, 32(9), 699–716. *http://dx.doi.org/10.1007/s40266-015-0292-7.*

[31] Hutton, D.W., Krein, S.L., Saint, S., Graves, N., Kolli, A., Lynem, R., & Mody, L. (2018). Economic evaluation of a catheter-associated urinary tract infection prevention program in nursing homes. Journal of the American Geriatrics Society, 66(4), 742–747. *http://dx.doi.org/10.1111/jgs.15316.*

[32] Nguyen, H.Q., Tunney, M.M., & Hughes, C.M. (2019). Interventions to Improve Antimicrobial Stewardship for Older People in Care Homes: A Systematic Review. *Drugs & aging, 36*(4), 355–369. *https://doi.org/10.1007/s40266-019-00637-0.*

[33] Sloane, P.D., Zimmerman, S., Ward, K., Kistler, C.E., Paone, D., Weber, D.J., Wretman, C.J., & Preisser, J.S. (2020). A 2-Year Pragmatic Trial of Antibiotic Stewardship in 27 Community Nursing Homes. *Journal of the American Geriatrics Society, 68*(1), 46–54. *https://doi.org/10.1111/jgs.16059.*

[34] Lee, M.H., Lee GA, Lee SH, Park YH (2019). Effectiveness and core components of infection prevention and control programmes in long-term care facilities: A systematic review. Retrieved from *https://pubmed.ncbi.nlm.nih.gov/30794854/.*

[35] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

Workgroup also agreed that the SNF HAI measure is suitable for use with rural providers in the SNF QRP. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

Additionally, measure testing was conducted on the SNF HAI measure. Split-half testing revealed the proposed measure's moderate reliability. Validity testing of the measure showed good model discrimination as the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix. The SNF HAI TEP also showed strong support for the face validity of the proposed measure. For measure testing details, refer to the document titled, Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.* This proposed measure is not currently NQF endorsed, but CMS plans to submit the measure for NQF endorsement in the future.

d. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by the entity with a contract under section 1890(a), currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed SNF HAI measure is not NQF endorsed, so we considered whether there are other available measures that assess HAIs in SNFs. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF endorsed measures for SNFs focused on capturing several types of severe infections attributable to the SNF setting in one composite score. For example, although the measures Percent of Residents with a Urinary Tract Infection (Long-Stay) (NQF #0684), National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infections (NQF #0138), NHSN Central Line-Associated Bloodstream Infections (NQF #0139), and NHSN Facility-Wide Inpatient Hospital-onset Clostridium Difficile Infection (NQF #1717) are NQF endorsed and all report on specific types of infections, they do not provide an overall HAI rate and are not specific to the SNF setting. Additionally, although the Skilled Nursing Facility 30-Day All-Cause Readmission measure (NQF #2510), the Potentially Preventable 30-Day Post-Discharge Readmission measure for SNF QRP, and the Skilled Nursing Facility 30-Day Potentially Preventable Readmission after Hospital Discharge measure (SNFPPR) are all specific to the SNF setting, they are not solely focused on infections. We intend to submit this proposed measure to the NQF for consideration of endorsement when feasible.

Therefore, after consideration of other available measures, we find that the exception under section 1899B(e)(2)(B) of the Act applies and are proposing the measure, Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAI) Requiring Hospitalization measure beginning with the FY 2023 SNF QRP.

e. Quality Measure Calculation

The proposed measure estimates the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization using 1 year of Medicare FFS claims data.

Both the proposed measure numerator and denominator are risk-adjusted. The measure's adjusted numerator is the estimated number of SNF stays predicted to have an HAI that results in hospitalization. The estimate starts with the observed count of the measure outcome, which is then risk-adjusted for resident characteristics and a statistical estimate of the SNF effect beyond resident case mix. The term ''SNF effect'' represents provider-specific behaviors that result in facilities' HAI rates. These behaviors may include adherence to evidence-based infection control policies and procedures. The adjusted denominator is the expected number of SNF stays with the measure outcome. The adjusted denominator is calculated by risk-adjusting the total eligible SNF stays for resident characteristics excluding the SNF effect.

The proposed measure is calculated using a standardized risk ratio (SRR) in which the predicted number of HAIs for SNF stays per provider is divided by the expected number of HAIs. For each SNF, a risk-adjusted rate of HAIs that are acquired during SNF care and result in hospitalization is calculated by multiplying the SRR by the overall national observed rate of HAIs for all SNF stays. The measure is risk-adjusted for age and gender characteristics, original reason for Medicare Entitlement, principal diagnosis during the prior proximal inpatient (IP) stay, types of surgery or procedure from the prior proximal IP stay, length of stay and ICU/CCU utilization from the prior proximal IP stay, dialysis treatment from the prior proximal IP stay, and HCC comorbidities and number of prior IP stays within 1 year preceding the SNF stay. For technical information about this proposed measure, including information about the measure calculation, risk adjustment, and exclusions, refer to the document titled, Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report available on the SNF QRP Measures and Technical Information page at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.* If this measure is finalized, we intend to publicly report this measure using four quarters of claims data. We refer readers to section VI.H.2. of this proposed rule for information regarding public reporting.

We invite public comment on our proposal to adopt the quality measure, the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalization, beginning with the FY 2023 SNF QRP.

2. Proposed COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 SNF QRP

a. Background

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS-CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[36] COVID–19 is a contagious

[36] U.S. Dept. of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at *https://*

respiratory infection [37] that can cause serious illness and death. Older individuals, racial and ethnic minorities, and those with underlying medical conditions are considered to be at higher risk for more serious complications from COVID–19.[38] [39] As of April 4, 2021 the U.S. reported over 30 million cases of COVID–19 and over 553,000 COVID–19 deaths.[40] Hospitals and health systems saw significant surges of COVID–19 patients as community infection levels increased.[41] In December 2020 and January 2021, media outlets reported that more than 100,000 Americans were in the hospital with COVID–19.[42]

Evidence indicates that COVID–19 primarily spreads when individuals are in close contact with one another.[43] The virus is typically transmitted through respiratory droplets or small particles created when someone who is infected with the virus coughs, sneezes, sings, talks or breathes.[44] Experts believe that COVID–19 spreads less commonly through contact with a contaminated surface [45] (although that is not thought to be a common way that COVID–19 spreads), and that in certain circumstances, infection can occur through airborne transmission.[46] According to the CDC, those at greatest risk of infection are persons who have had prolonged, unprotected close contact (that is, within 6 feet for 15 minutes or longer) with an individual with confirmed SARS-CoV–2 infection, regardless of whether the individual has symptoms.[47] Although personal protective equipment (PPE) and other infection-control precautions can reduce the likelihood of transmission in health care settings, COVID–19 can spread between healthcare personnel (HCP) and patients given the close contact that may occur during the provision of care.[48] The CDC has emphasized that health care settings, including long-term care settings, can be high-risk places for COVID–19 exposure and transmission.[49]

Vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19 and ultimately help restore societal functioning.[50]

On December 11, 2020, the Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for a COVID–19 vaccine in the U.S.[51] Subsequently, the FDA issued EUAs for additional COVID–19 vaccines. In issuing these EUAs, the FDA determined that it was reasonable to conclude that the known and potential benefits of each vaccine, when used as authorized to prevent COVID–19, outweighed its known and potential risks.[52] [53] [54]

As part of its national strategy to address COVID–19, the current administration stated that it would work with states and the private sector to execute an aggressive vaccination strategy and has outlined a goal of administering 200 million shots in 100 days.[55] Although the goal of the U.S. government is to ensure that every American who wants to receive a COVID–19 vaccine can receive one, Federal agencies recommended that early vaccination efforts focus on those critical to the PHE response, including healthcare personnel (HCP), and individuals at highest risk for developing severe illness from COVID–19.[56] For example, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended that HCP should be among those individuals prioritized to receive the initial, limited supply of the COVID–19 vaccination, given the potential for transmission in health care settings and the need to preserve health care system capacity.[57] Research suggests most states followed this recommendation,[58] and HCP began

www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.

[37] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[38] Centers for Disease Control and Prevention (2021). Health Equity Considerations and Racial and Ethnic Minority Groups. Available at *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[39] Centers for Disease Control and Prevention. (2020). Your Health: Symptoms of Coronavirus. Available at *https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.*

[40] Centers for Disease Control and Prevention. (2020). CDC COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days.*

[41] Associated Press. Tired to the Bone. Hospitals Overwhelmed with Virus Cases. November 18, 2020. Accessed on December 16, 2020, at *https://apnews.com/article/hospitals-overwhelmed-coronavirus-cases-74a1f0dc3634917a5dc13408455cd895.* Also see: New York Times. Just how full are U.S. intensive care units? New data paints an alarming picture. November 18, 2020. Accessed on December 16, 2020, at *https://www.nytimes.com/2020/12/09/world/just-how-full-are-us-intensive-care-units-new-data-paints-an-alarming-picture.html.*

[42] NPR. U.S. Hits 100,000 COVID–19 Hospitalizations, Breaks Daily Death Record. Dec. 2, 2020. Accessed on December 17, 2020 at *https://www.npr.org/sections/coronavirus-live-updates/2020/12/02/941902471/u-s-hits-100-000-covid-19-hospitalizations-breaks-daily-death-record;* The Wall Street Journal. Coronavirus Live Updates: U.S. Hospitalizations, Newly Reported Cases, Deaths Edge Downward. Accessed on January 11 at *https://www.wsj.com/livecoverage/covid-2021-01-11.*

[43] Centers for Disease Control and Prevention. (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[44] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[45] Centers for Disease Control and Prevention (2021). COVID–19. Your Health. Frequently Asked Questions. Accessed on January 11, 2021 at *https://www.cdc.gov/coronavirus/2019-ncov/faq.html.*

[46] Centers for Disease Control and Prevention. (2020). Centers for Disease Control Scientific Brief: SARS-CoV–2 and Potential Airborne Transmission. Available at *https://www.cdc.gov/coronavirus/2019-ncov/more/scientific-brief-sars-cov-2.html.*

[47] Centers for Disease Control and Prevention. (2020). Clinical Questions about COVID–19: Questions and Answers. Accessed on December 2, 2020 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html.*

[48] Centers for Disease Control and Prevention. (2020). Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID–19. Accessed on December 2 at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html.*

[49] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb Mortal Wkly Rep. 2020; 69(49): 1857–1859.

[50] Centers for Disease Control and Prevention. (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed on December 18 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[51] U.S. Food and Drug Administration. (2020). Pfizer-BioNTech COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144412/download.*

[52] Ibid.

[53] U.S. Food and Drug Administration. (2021). ModernaTX, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/144636/download.*

[54] U.S. Food and Drug Administration (2020). Janssen Biotech, Inc. COVID–19 Vaccine EUA Letter of Authorization. Available at *https://www.fda.gov/media/146303/download.*

[55] The White House. Remarks by President Biden on the COVID–19 Response and the State of Vaccinations. March 29, 2021. Accessed at *https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/03/29/remarks-by-president-biden-on-the-covid-19-response-and-the-state-of-vaccinations/.*

[56] Health and Human Services, Department of Defense. (2020) From the Factory to the Frontlines: The Operation Warp Speed Strategy for Distributing a COVID–19 Vaccine. Accessed December 18 at *https://www.hhs.gov/sites/default/files/strategy-for-distributing-covid-19-vaccine.pdf;* Centers for Disease Control (2020). COVID–19 Vaccination Program Interim Playbook for Jurisdiction Operations. Accessed December 18 at *https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf.*

[57] Dooling, K, McClung, M, et al. ''The Advisory Committee on Immunization Practices' Interim Recommendations for Allocating Initial Supplies of COVID–19 Vaccine—United States, 2020.'' Morb. Mortal Wkly Rep. 2020; 69(49): 1857–1859. ACIP also recommended that long-term care residents be prioritized to receive the vaccine, given their age, high levels of underlying medical conditions, and congregate living situations make them high risk for severe illness from COVID–19.

[58] Kates, J, Michaud, J, Tolbert, J. ''How Are States Prioritizing Who Will Get the COVID–19 Vaccine First?'' Kaiser Family Foundation. December 14, 2020. Accessed on December 16 at *https://www.kff.org/policy-watch/how-are-states-prioritizing-who-will-get-the-covid-19-vaccine-first/.*

receiving the vaccine in mid-December of 2020.[59]

HCP are at risk of carrying COVID–19 infection to patients, experiencing illness or death as a result of COVID–19 themselves, and transmitting it to their families, friends, and the general public. We believe it is important to require that SNFs report HCP vaccination in order to assess whether they are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of SNFs to continue serving their communities throughout the PHE and beyond. Currently, as required under the May 8, 2020 Interim final rule with comment period (85 FR 27601–27602), SNFs are required to submit COVID–19 data through the CDC's NHSN Long-term Care Facility COVID–19 Module of the NHSN. Examples of data reported in the module include: suspected and confirmed COVID–19 infections among residents and staff, including residents previously treated for COVID–19; total deaths and COVID–19 deaths among residents and staff; personal protective equipment and hand hygiene supplies in the facility; ventilator capacity and supplies available in the facility; resident beds and census; access to COVID–19 testing while the resident is in the facility; and staffing shortages. Although HCP and resident COVID–19 vaccination data reporting modules are currently available through the NHSN, the reporting of this data is voluntary. [60]

We also believe that publishing facility-level COVID–19 HCP vaccination rates on Care Compare would be helpful to many patients, including those who are at high-risk for developing serious complications from COVID–19, as they choose facilities from which to seek treatment. Under CMS' Meaningful Measures Framework, the COVID–19 Vaccination Coverage among Healthcare Personnel measure addresses the quality priority of ''Promote Effective Prevention & Treatment of Chronic Disease'' through the Meaningful Measures Area of ''Preventive Care.''

Therefore, we are proposing a new measure, COVID–19 Vaccination Coverage among HCP to assess the proportion of a SNF's healthcare workforce that has been vaccinated against COVID–19.

b. Stakeholder Input

In the development and specification of the measure, a transparent process was employed to seek input from stakeholders and national experts and engage in a process that allows for pre-rulemaking input on each measure, under section 1890A of the Act.[61] To meet this requirement, the following opportunity was provided for stakeholder input.

The pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List that the Secretary is considering adopting, through Federal rulemaking process, for use in Medicare program(s). This allows multi-stakeholder groups to provide recommendations to the Secretary on the measures included on the list. The COVID–19 Vaccination Coverage among Healthcare Personnel measure was included on the publicly available ''List of Measures under Consideration for December 21, 2020'' (MUC List).[62] Five comments were received from industry stakeholders during the pre-rulemaking process on the COVID–19 Vaccination Coverage among HCP measure, and support was mixed. Commenters generally supported the concept of the measure. However, there was concern about the availability of the vaccine and measure definition for HCP, and some commenters encouraged CMS to continue to update the measure as new evidence comes in.

c. Measure Applications Partnership (MAP) Review

When the Measure Applications Partnership (MAP) PAC–LTC Workgroup convened on January 11, 2021, it reviewed the MUC List and the COVID–19 Vaccination Coverage among HCP measure. The MAP recognized that the proposed measure represents a promising effort to advance measurement for an evolving national pandemic and that it would bring value to the SNF QRP measure set by providing transparency about an important COVID–19 intervention to help limit COVID–19 infections.[63] The MAP also stated that collecting information on COVID–19 vaccination coverage among healthcare personnel and providing feedback to facilities would allow facilities to benchmark coverage rates and improve coverage in their facility, and that reducing rates of COVID–19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness.[64]

In its preliminary recommendations, the MAP PAC–LTC Workgroup did not support this measure for rulemaking, subject to potential for mitigation.[65] To mitigate its concerns, the MAP believed that the measure needed well-documented evidence, finalized specifications, testing, and NQF endorsement prior to implementation.[66] Subsequently, the MAP Coordinating Committee met on January 25, 2021, and reviewed the COVID–19 Vaccination Coverage among Healthcare Personnel measure. In the 2020–2021 MAP Final Recommendations, the MAP offered conditional support for rulemaking contingent on CMS bringing the measure back to the MAP once the specifications are further clarified. The final MAP report is available at *http://www.qualityforum.org/Publications/2021/03/MAP_2020-2021_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx.*

In response to the MAP request for CMS to bring the measure back once the specifications were further clarified, CMS met with the MAP Coordinating Committee on March 15, 2021. First, CMS and CDC clarified the alignment of the COVID–19 Vaccination Coverage among HCP with the Influenza Vaccination Coverage among HCP (NQF #0431), an NQF-endorsed measure since 2012. The COVID–19 Vaccination Coverage among HCP measure is calculated using the same approach as the Influenza Vaccination Coverage among HCP measure.[67] The approach to identifying HCPs eligible for the COVID–19 vaccination is analogous to those used in the NQF endorsed flu measure which underwent rigorous review from technical experts about the validity of that approach and for which

[59] Associated Press. 'Healing is Coming:' US Health Workers Start Getting Vaccine. December 15, 2020. Accessed on December 16 at *https://apnews.com/article/us-health-workers-coronavirus-vaccine-56df745388a9fc12ae93c6f9a0d0e81f.*

[60] Centers for Disease Control and Prevention. Weekly COVID–19 Vaccination Data Reporting. Accessed at *https://www.cdc.gov/nhsn/ltc/weekly-covid-vac/index.html.*

[61] Centers for Medicare & Medicaid Services. Pre-rulemaking. Accessed at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityMeasures/Pre-Rulemaking.*

[62] National Quality Forum. List of Measures Under Consideration for December 21, 2020. Accessed at *https://www.cms.gov/files/document/measures-under-consideration-list-2020-report.pdf* on January 12, 2021.

[63] Measure Applications Partnership. MAP Preliminary Recommendations 2020–2021. Accessed on February 3, 2021 at *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=94650.*

[64] Ibid.

[65] Ibid.

[66] Ibid.

[67] The Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

ultimately received NQF endorsement. More recently, prospective cohorts of health care personnel, first responders, and other essential and frontline workers over 13 weeks in eight U.S. locations confirmed that authorized COVID–19 vaccines are highly effective in real-world conditions. Vaccine effectiveness of full immunization with two doses of vaccines was 90 percent.[68]

Additionally, to support the measure's data element validity, CDC conducted testing of the COVID–19 vaccination numerator using data collected through the NHSN and independently reported through the Federal Pharmacy Partnership for Long-term Care Program for delivering vaccines to long-term care facilities. These are two completely independent data collection systems. In initial analyses of the first month of vaccination, the number of HCP vaccinated in approximately 1,200 facilities which had data from both systems, the number of HCP vaccinated was highly correlated between these two systems with a correlation coefficient of nearly 90 percent in the second two weeks of reporting. Of note, assessment of data element reliability may not be required by NQF if data element validity is demonstrated.[69] To assess the validity of new performance measure score (in this case, percentage of COVID–19 vaccination coverage), NQF allows assessment by face validity (that is, subjective determination by experts that the measure appears to reflect quality of care, done through a systematic and transparent process),[70] and the MAP concurred with the face validity of the COVID–19 Vaccination Coverage among HCP measure. Materials from the March 15, 2021 MAP Coordinating Committee meeting are on the NQF website at *https://www.qualityforum.org/ProjectMaterials.aspx?projectID=75367.*

This measure is not NQF endorsed, but the CDC, in collaboration with CMS, plans to submit the measure for NQF endorsement in the future.

d. Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that absent an exception under section 1899B(e)(2)(B) of the Act, each measure specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, currently the National Quality Forum (NQF). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The proposed COVID–19 Vaccination Coverage among HCP measure is not currently NQF endorsed and has not been submitted to the NQF for consideration, so we considered whether there are other available measures that assess COVID–19 vaccinations among HCP. After review of the NQF's consensus-endorsed measures, we were unable to identify any NQF endorsed measures for SNFs focused on capturing COVID–19 vaccination coverage of HCP, and we found no other feasible and practical measure on the topic of COVID–19 vaccination coverage among HCP. The only other vaccination coverage of HCP measure found was the Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) measure which is NQF endorsed and was adopted in the IRF QRP in the FY 2014 IRF PPS Final Rule (78 FR 47905 through 47906), and in the LTCH QRP in the FY 2013 IPPS/LTCH PPS Final Rule (77 FR 53630 through 53631).

Given the novel nature of the SARS-CoV–2 virus, and the significant and immediate risk it poses in SNFs, we believe it is necessary to propose the measure as soon as possible. Therefore, after consideration of other available measures that assess COVID–19 vaccination rates among HCP, we believe the exception under section 1899B(e)(2)(B) of the Act applies. This proposed measure has the potential to generate actionable data on vaccination rates that can be used to target quality improvement among SNF providers.

e. Quality Measure Calculation

The COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in facilities such as SNFs. Since this proposed measure is a process measure, rather than an outcome measure, it does not require risk-adjustment.

The denominator would be the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC.[71] While the SNF QRP applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals, we believe it is necessary to include all HCP within the facility in the measure denominator because all HCP would have access to and may interact with SNF residents.

The numerator would be the cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who received a complete vaccination course against SARS–CoV–2. A complete vaccination course may require one or more doses depending on the specific vaccine used. The finalized measure specifications are on the CDC website at *https://www.cdc.gov/nhsn/nqf/index.html.*

We propose that SNFs would submit data for the measure through the CDC/NHSN data collection and submission framework.[72] SNFs would use the COVID–19 vaccination data reporting module in the NHSN Healthcare Personnel Safety (HPS) Component to report the number of HCP eligible who have worked at the facility that week (denominator) and the number of those HCP who have received a completed COVID–19 vaccination course (numerator). SNFs would submit COVID–19 vaccination data for at least 1 week each month. If SNFs submit more than 1 week of data in a month, the most recent week's data would be used for measure calculation purposes. Each quarter, the CDC would calculate a summary measure of COVID–19 vaccination coverage from the 3 monthly modules of data reported for the quarter. This quarterly rate would be publicly reported on the Care Compare website. Subsequent to the first refresh, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data on Care Compare.

For purposes of submitting data to CMS for the FY 2023 SNF QRP, SNFs

[68] Centers for Disease Control and Preventions. Morbidity and Mortality Weekly Report. March 29, 2021. Available at *https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm?s_cid=mm7013e3_w.*

[69] National Quality Form. Key Points for Evaluating Scientific Acceptability. Revised January 3, 2020. *https://www.qualityforum.org/Measuring_Performance/Scientific_Methods_Panel/Docs/Evaluation_Guidance.aspx#:~:text=NQF%20is%20not%20prescriptive%20about,reliability%20or%20validity%20testing%20results.&text=Reliability%20and%20validity%20must%20be,source%20and%20level%20of%20analysis*).

[70] Ibid.

[71] Centers for Disease Control and Prevention. Interim Clinical Considerations for Use of COVID–19 Vaccines Currently Authorized in the United Sates. Contraindications found in Appendix B: Triage of people presenting for the vaccination. Accessed at *https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.*

[72] Centers for Disease Control and Prevention. Surveillance for Weekly HCP COVID–19 Vaccination. Accessed at *https://www.cdc.gov/nhsn/hps/weekly-covid-vac/index.html* on February 10, 2021.

would be required to submit data for the period October 1, 2021 through December 31, 2021. Following the initial data submission quarter for the FY 2023 SNF QRP, subsequent compliance for the SNF QRP would be based on four quarters of such data submission. For more information on the measure's proposed public reporting period, we refer readers to section VI.H.3. of this proposed rule.

We invite public comment on our proposal to add a new measure, COVID–19 Vaccination Coverage among Healthcare Personnel, to the SNF QRP beginning with the FY 2023 SNF QRP.

3. Proposed Update to the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure Beginning With the FY 2023 SNF QRP

We are proposing to update the Transfer of Health Information to the Patient—Post-Acute Care (PAC) measure denominator to exclude residents discharged home under the care of an organized home health service or hospice. This measure assesses for and reports on the timely transfer of health information, specifically transfer of a medication list. We adopted this measure in the FY 2020 SNF PPS final rule (84 FR 38761 through 38764) beginning with the FY 2022 SNF QRP. It is a process-based measure that evaluates for the transfer of information when a resident is discharged from his or her current PAC setting to a private home/apartment, board and care home, assisted living, group home, transitional living, or home under the care of an organized home health service organization or hospice.

This measure, adopted under section 1899B(c)(1)(E) of the Act, was developed to be a standardized measure for the IRF QRP, LTCH QRP, SNF QRP, and Home Health (HH) QRP. The measure is calculated by one standardized data element that asks, ''At the time of discharge, did the facility provide the resident's current reconciled medication list to the resident, family, and/or caregiver?'' The discharge location is captured by items on the Minimum Data Set (MDS).

Specifically, we are proposing to update the measure denominator. Currently, the measure denominators for both the TOH-Patient and the TOH-Provider measure assess the number of residents discharged home under the care of an organized home health service organization or hospice. In order to align the measure with the IRF QRP, LTCH QRP and HH QRP and avoid counting the resident in both TOH measures in the SNF QRP, we are proposing to remove this location from the definition of the denominator for the TOH-Patient measure. Therefore, we are proposing to update the denominator for the TOH-Patient measure to only discharges to a private home/apartment, board and care home, assisted living, group home, or transitional living. For additional technical information regarding the TOH-Patient measure, we refer readers to the document titled ''Final Specifications for SNF QRP Quality Measures and Standardized Patient Assessment Data Elements (SPADEs)'' available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/Final-Specifications-for-SNF-QRP-Quality-Measures-and-SPADEs.pdf.*

We invite public comment on our proposal to update the denominator of the Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) measure beginning with the FY 2023 SNF QRP.

D. SNF QRP Quality Measures Under Consideration for Future Years: Request for Information (RFI)

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the measures and concepts under consideration listed in Table 27 for future years in the SNF QRP.

TABLE 27—FUTURE MEASURES AND MEASURE CONCEPTS UNDER CONSIDERATION FOR THE SNF QRP

Assessment-based quality measures and measure concepts
Frailty.
Patient reported outcomes.
Shared decision making process.
Appropriate pain assessment and pain management processes.
Health equity.

While we will not be responding to specific comments submitted in response to this Request for Information (RFI) in the FY 2022 SNF PPS final rule, we intend to use this input to inform our future measure development efforts.

E. Fast Healthcare Interoperability Resources (FHIR) in Support of Digital Quality Measurement in Quality Programs—Request for Information (RFI)

1. Background

The SNF QRP is authorized by section 1888(e)(6) of the Act and furthers our mission to improve the quality of health care for beneficiaries through measurement, transparency, and public reporting of data. The SNF QRP and CMS's other quality programs are foundational for contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. In October 2017, we launched the Meaningful Measures Framework. This framework captures our vision to address health care quality priorities and gaps, including emphasizing digital quality measurement (dQM), reducing measurement burden, and promoting patient perspectives, while also focusing on modernization and innovation. The scope of the Meaningful Measures Framework has evolved to accommodate the changes in the health care environment, initially focusing on measure and burden reduction to include the promotion of innovation and modernization of all aspects of quality.[73] There is a need to streamline our approach to data collection, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, improvement, and learning.

In alignment with Meaningful Measures 2.0, we are seeking feedback on our future plans to define digital quality measures (dQMs) for the SNF QRP. We also are seeking feedback on the potential use of Fast Healthcare Interoperable Resources (FHIR) for dQMs within the SNF QRP aligning where possible with other quality programs. FHIR is a free and open source standards framework (in both commercial and government settings) created by Health Level Seven International (HL7®) that establishes a common language and process for all health information technology.

2. Definition of Digital Quality Measures

We are considering adopting a standardized definition of Digital Quality Measures (dQMs) in alignment across quality programs, including the SNF QRP. We are considering in the future to propose the adoption within the SNF QRP the following definition: Digital Quality Measures (dQMs) are quality measures that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems.[74] A dQM includes a calculation that processes digital data to produce a measure score or measure scores. Data sources for dQMs may

[73] Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[74] Definition taken from the CMS Quality Conference 2021.

include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources. As an example, the quality measures calculated from patient assessment data submitted electronically to CMS would be considered digital quality measures.

3. Use of FHIR for Future dQMs in the SNF QRP

One of the first areas CMS has identified relative to improving our digital strategy is through the use of Fast Healthcare Interoperability Resources (FHIR)-based standards to exchange clinical information through application programming interfaces (APIs), aligning with other programs where possible, to allow clinicians to digitally submit quality information one time that can then be used in many ways. We believe that in the future proposing such a standard within the SNF QRP could potentially enable collaboration and information sharing, which is essential for delivering high-quality care and better outcomes at a lower cost.

We are currently evaluating the use of FHIR based APIs to access assessment data collected and maintained through the Quality Improvement and Evaluation System (QIES) and internet QIES (iQIES) health information systems and are working with healthcare standards organizations to assure that their evolving standards fully support our assessment instrument content. Further, as more SNFs are adopting EHRs, we are evaluating using the FHIR interfaces for accessing patient data (including standard assessments) directly from SNF EHRs. Accessing data in this manner could also enable the exchange of data for purposes beyond data reporting to CMS, such as care coordination further increasing the value of EHR investments across the healthcare continuum. Once providers map their EHR data to a FHIR API in standard FHIR formats it could be possible to send and receive the data needed for measures and other uses from their EHRs through FHIR APIs.

4. Future Alignment of Measures Across Reporting Programs, Federal and State Agencies, and the Private Sector

We are committed to using policy levers and working with stakeholders to achieve interoperable data exchange and to transition to full digital quality measurement in our quality programs. We are considering the future potential development and staged implementation of a cohesive portfolio of dQMs across our quality programs (including the SNF QRP), agencies, and private payers. This cohesive portfolio would require, where possible, alignment of: (1) Measure concepts and specifications including narrative statements, measure logic, and value sets; and (2) the individual data elements used to build these measure specifications and calculate the measures. Further, the required data elements would be limited to standardized, interoperable elements to the fullest extent possible; hence, part of the alignment strategy will be the consideration and advancement of data standards and implementation guides for key data elements. We would coordinate closely with quality measure developers, Federal and state agencies, and private payers to develop and to maintain a cohesive dQM portfolio that meets our programmatic requirements and that fully aligns across Federal and state agencies and payers to the extent possible.

We intend this coordination to be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, patient reported outcomes (PROs), disparities, care coordination), and track with the transformation of data collection. This includes conformance with standards and health IT module updates, future adoption of technologies incorporated within the ONC Health IT Certification Program and may also include standards adopted by ONC (for example, to enable standards-based APIs). The coordination would build on the principles outlined in HHS' Nation Health Quality Roadmap.[75] It would focus on the quality domains of safety, timeliness, efficiency, effectiveness, equitability, and patient-centeredness. It would leverage several existing Federal and public-private efforts including our Meaningful Measures 2.0 Framework; the Federal Electronic Health Record Modernization (DoD/VA); the Core Quality Measure Collaborative, which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, NQF, provider organizations, private payers, and consumers and develops consensus on quality measures for provider specialties; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. We would coordinate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health. Through this coordination, we would identify which existing measures could be used or evolved to be used as dQMs, in recognition of current healthcare practice and priorities.

This multi-stakeholder, joint Federal, state, and industry effort, made possible and enabled by the pending advances towards true interoperability, would yield a significantly improved quality measurement enterprise. The success of the dQM portfolio would be enhanced by the degree to which the measures achieve our programmatic requirements as well as the requirements of other agencies and payers.

5. Solicitation of Comments

We seek input on the following steps that would enable transformation of CMS' quality measurement enterprise to be fully digital:

- What EHR/IT systems do you use and do you participate in a health information exchange (HIE)?
- How do you currently share information with other providers?
- In what ways could we incentivize or reward innovative uses of health information technology (IT) that could reduce burden for post-acute care settings, including but not limited to SNFs?
- What additional resources or tools would post-acute care settings, including but not limited to SNFs, and health IT vendors find helpful to support the testing, implementation, collection, and reporting of all measures using FHIR standards via secure APIs to reinforce the sharing of patient health information between care settings?
- Would vendors, including those that service post-acute care settings, such as SNFs, be interested in or willing to participate in pilots or models of alternative approaches to quality measurement that would align standards for quality measure data collection across care settings to improve care coordination, such as sharing patient data via secure FHIR API as the basis for calculating and reporting digital measures?

We plan to continue working with other agencies and stakeholders to coordinate and to inform our transformation to dQMs leveraging health IT standards. While we will not be responding to specific comments submitted in response to this RFI in the FY 2022 SNF PPS final rule, we will

[75] Department of Health and Human Services. National Health Quality Roadmap. May 15, 2020. Available at *https://www.hhs.gov/sites/default/files/national-health-quality-roadmap.pdf.*

actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. Any updates to specific program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

F. Closing the Health Equity Gap in Post-Acute Care Quality Reporting Programs—Request for Information (RFI)

1. Background

Significant and persistent inequities in health outcomes exist in the United States. In recognition of persistent health disparities and the importance of closing the health equity gap, we request information on revising several CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for providers and patients. Belonging to a racial or ethnic minority group; living with a disability; being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; or being near or below the poverty level is often associated with worse health outcomes.[76] [77] [78] [79] [80] [81] [82] [83] Such disparities in health outcomes are the result of a number of factors, but importantly for CMS programs, although not the sole determinant, poor access and provision of lower quality health care contribute to health disparities. For instance, numerous studies have shown that among Medicare beneficiaries, racial and ethnic minority individuals often receive lower quality of care, report lower experiences of care, and experience more frequent hospital readmissions and operative complications.[84] [85] [86] [87] [88] [89]

Readmission rates for common conditions in the Hospital Readmissions Reduction Program are higher for black Medicare beneficiaries and higher for Hispanic Medicare beneficiaries with Congestive Heart Failure and Acute Myocardial Infarction.[90] [91] [92] [93] [94] Studies have also shown that African Americans are significantly more likely than white Americans to die prematurely from heart disease and stroke.[95] The COVID–19 pandemic has further illustrated many of these longstanding health inequities with higher rates of infection, hospitalization, and mortality among black, Latino, and Indigenous and Native American persons relative to white persons.[96] [97] As noted by the Centers for Disease Control ''long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID–19''.[98] One important strategy for addressing these important inequities is by improving data collection to allow for better measurement and reporting on equity across post-acute care programs and policies.

We are also committed to achieving equity in health care outcomes for our beneficiaries by supporting providers in quality improvement activities to reduce health inequities, enabling them to make more informed decisions, and promoting provider accountability for health care disparities.[99] [100] For the purposes of this rule, we are using a definition of equity established in Executive Order 13985, as ''the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality.'' [101] We note that this definition was recently established by the current administration, and provides a useful, common definition for equity across different areas of government, although numerous other definitions of equity exist.

Our ongoing commitment to closing the equity gap in CMS quality programs is demonstrated by a portfolio of programs aimed at making information

[76] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011; 305(7):675–681.

[77] Lindenauer PK, Lagu T, Rothberg MB, et al. Income Inequality and 30 Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. British Medical Journal. 2013; 346.

[78] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[79] Polyakova, M., et al. Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. Health Affairs. 2021; 40(2): 307–316.

[80] Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018.

[81] *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[82] *www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.*

[83] Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[84] Martino, SC, Elliott, MN, Dembosky, JW, Hambarsoomian, K, Burkhart, Q, Klein, DJ, Gildner, J, and Haviland, AM. Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage. Baltimore, MD: CMS Office of Minority Health. 2020.

[85] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[86] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. Racial disparities in knee and hip total joint arthroplasty: an 18-year analysis of national Medicare data. Ann Rheum Dis. 2014 Dec;73(12):2107–15.

[87] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc. 2019 Aug;67(8):1672–1679.

[88] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[89] Tsai TC, Orav EJ, Joynt KE. Disparities in surgical 30-day readmission rates for Medicare beneficiaries by race and site of care. Ann Surg. Jun 2014;259(6):1086–1090.

[90] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. Readmission rates for Hispanic Medicare beneficiaries with heart failure and acute myocardial infarction. Am Heart J. Aug 2011;162(2):254–261 e253.

[91] Centers for Medicare and Medicaid Services. Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures; 2014.

[92] Guide to Reducing Disparities in Readmissions. CMS Office of Minority Health. Revised August 2018. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[93] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. Chronic obstructive pulmonary disease readmissions at minority-serving institutions. Ann Am Thorac Soc. Dec 2013;10(6):680–684.

[94] Joynt KE, Orav E, Jha AK. Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA. 2011;305(7):675–681.

[95] HHS. Heart disease and African Americans. (March 29, 2021). *https://www.minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=19.*

[96] *https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet.pdf.*

[97] Ochieng N, Cubanski J, Neuman T, Artiga S, and Damico A. Racial and Ethnic Health Inequities and Medicare. Kaiser Family Foundation. February 2021. Available at *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/.*

[98] *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html.*

[99] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.*

[100] Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.*

[101] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-Federal-government.*

on the quality of health care providers and services, including disparities, more transparent to consumers and providers. The CMS Equity Plan for Improving Quality in Medicare outlines a path to equity which aims to support Quality Improvement Networks and Quality Improvement Organizations (QIN–QIOs); Federal, state, local, and tribal organizations; providers; researchers; policymakers; beneficiaries and their families; and other stakeholders in activities to achieve health equity. The CMS Equity Plan includes three core elements: (1) Increasing understanding and awareness of disparities; (2) developing and disseminating solutions to achieve health equity; and (3) implementing sustainable actions to achieve health equity.[102] The CMS Quality Strategy and Meaningful Measures Framework [103] include elimination of racial and ethnic disparities as a central principle. Our ongoing commitment to closing the health equity gap in the SNF QRP is demonstrated by the adoption of standardized patient assessment data elements (SPADEs) which include several social determinants of health (SDOH) that were finalized in the FY 2020 SNF PPS final rule for the SNF QRP (84 FR 38805 through 38817).

We continue to work with Federal and private partners to better leverage data on social risk to improve our understanding of how these factors can be better measured in order to close the health equity gap. Among other things, we have developed an Inventory of Resources for Standardized Demographic and Language Data Collection [104] and supported collection of specialized International Classification of Disease, 10th Edition, Clinical Modification (ICD–10–CM) codes for describing the socioeconomic, cultural, and environmental determinants of health. We continue to work to improve our understanding of this important issue and to identify policy solutions that achieve the goals of attaining health equity for all patients.

2. Solicitation of Public Comment

Under authority of the IMPACT Act and section 1888(e)(6) of the Act, we are seeking comment on the possibility of revising measure development, and the collection of other SPADEs that address gaps in health equity in the SNF QRP. Any potential health equity data collection or measure reporting within a CMS program that might result from public comments received in response to this solicitation would be addressed through a separate notice-and-comment rulemaking in the future.

Specifically, we are inviting public comment on the following:

- Recommendations for quality measures, or measurement domains that address health equity, for use in the SNF QRP.
- As finalized in the FY 2020 SNF PPS final rule (84 FR 38805 through 38817), SNFs must report certain standardized patient assessment data elements (SPADEs) on SDOH, including race, ethnicity, preferred language, interpreter services, health literacy, transportation and social isolation.[105] CMS is seeking guidance on any additional items, including SPADEs that could be used to assess health equity in the care of SNF residents, for use in the SNF QRP.
- Recommendations for how CMS can promote health equity in outcomes among SNF residents. For example, we are interested in feedback regarding whether including facility-level quality measure results stratified by social risk factors and social determinants of health (for example, dual eligibility for Medicare and Medicaid, race) in confidential feedback reports could allow facilities to identify gaps in the quality of care they provide. (For example, methods similar or analogous to the CMS Disparity Methods [106] which provide hospital-level confidential results stratified by dual eligibility for condition-specific readmission measures, which are currently included in the Hospital Readmission Reduction Program (see 84 FR 42496 through 42500)).
- Methods that commenters or their organizations use in employing data to reduce disparities and improve patient outcomes, including the source(s) of data used, as appropriate.
- Given the importance of structured data and health IT standards for the capture, use, and exchange of relevant health data for improving health equity, the existing challenges providers' encounter for effective capture, use, and exchange of health information, including data on race, ethnicity, and other social determinants of health, to support care delivery and decision making.

While we will not be responding to specific comments submitted in response to this RFI in the FY 2022 SNF PPS final rule, we intend to use this input to inform future policy development. We look forward to receiving feedback on these topics, and note for readers that responses to the RFI should focus on how they could be applied to the quality reporting program requirements. Please note that any responses provided will not impact payment decisions.

G. Form, Manner, and Timing of Data Submission Under the SNF QRP

1. Background

We refer readers to the regulatory text at 42 CFR 413.360(b) for information regarding the current policies for reporting SNF QRP data.

2. Proposed Schedule for Data Submission of the SNF HAI Measure Beginning With the FY 2023 QRP

The SNF HAI measure, which we propose in section VI.C.1. of this proposed rule, is a Medicare FFS claims-based measure. Because claims-based measures can be calculated based on data that have already been submitted to the Medicare program for payment purposes, no additional information collection would be required from SNFs. We are proposing to use 1 year of FY 2019 claims data (October 1, 2018 through September 30, 2019) for the FY 2023 SNF QRP. We are proposing to use FY 2019 data to calculate this measure because it is the most recent fiscal year of data that has not been exempted due to the PHE. Beginning with the FY 2024 SNF QRP, compliance with APU reporting requirements would use FY 2021 claims data (October 1, 2020 through September 30, 2021) and advance by one FY with each annual refresh. Due to the fact that Q1 and Q2 2020 data were excepted by CMS related to the COVID–19 PHE, these quarters of data would not be used for purposes of the QRP. For information on public reporting of the SNF HAI measure, we refer you to Table 31 in section VI.H.4.c. of this proposed rule.

We invite public comment on this proposal.

[102] Centers for Medicare & Medicaid Services Office of Minority Health. The CMS Equity Plan for Improving Quality in Medicare. *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf.*

[103] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/MMF/General-info-Sub-Page.*

[104] Centers for Medicare and Medicaid Services. Building an Organizational Response to Health Disparities Inventory of Resources for Standardized Demographic and Language Data Collection. 2020. *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Collection-Resources.pdf.*

[105] In response to the COVID–19 PHE, CMS released an Interim Final Rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the SDOH for at least two full fiscal years after the end of the PHE.

[106] *https://qualitynet.cms.gov/inpatient/measures/disparity-methods/methodology.*

3. Proposed Method of Data Submission for COVID–19 Vaccination Coverage Among Healthcare Personnel Measure

As discussed in section VI.C.2 of this proposed rule, we propose to require that SNFs submit data on the COVID–19 Vaccination Coverage among Healthcare Personnel Measure through the Centers for Disease Control and Prevention (CDC)/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained by the CDC that can be utilized by all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers, and SNFs. The NHSN enables healthcare facilities to collect and use vaccination data, and information on other adverse events. NHSN collects data via a Web-based tool hosted by the CDC (*http://www.cdc.gov/*). The NHSN is provided free of charge. We propose for SNFs to submit the data needed to calculate the COVID–19 Vaccination Coverage among Healthcare Personnel measure using the NHSN's standard data submission requirements. CDC/NHSN requirements include adherence to training requirements, use of CDC measure specifications, data element definitions, data submission requirements and instructions, data submission timeframes, as well as NHSN participation forms and indications to CDC allowing CMS to access data for this measure for the SNF quality reporting program purposes. Detailed requirements for NHSN participation, measure specifications, and data collection can be found at *http://www.cdc.gov/nhsn/.* We propose to require SNFs to use the specifications and data collection tools for the proposed COVID–19 Vaccination Coverage among Healthcare Personnel measure as required by CDC as of the time that the data are submitted.

We invite public comment on this proposal.

4. Proposed Schedule for Data Submission of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure Beginning With the FY 2023 SNF QRP

As discussed in section VI.C.2. of this proposed rule, we are proposing to adopt the COVID–19 Vaccination Coverage among HCP quality measure beginning with the FY 2023 SNF QRP. Given the time-sensitive nature of this measure in light of the PHE, we propose an initial data submission period from October 1, 2021 through December 31, 2021. Starting in CY 2022, SNFs would be required to submit data for the entire calendar year beginning with the FY 2024 SNF QRP.

SNFs would submit data for the measure through the CDC/NHSN web-based surveillance system. SNFs would use the COVID–19 vaccination data collection module in the NHSN Long-term Care (LTC) Component to report the cumulative number of HCP eligible to work in the healthcare facility for at least 1 day during the reporting period, excluding persons with contraindications to COVID–19 vaccination (denominator) and the cumulative number of HCP eligible to work in the SNF for at least 1 day during the reporting period and who received a complete vaccination course against COVID–19 (numerator). SNFs would submit COVID–19 vaccination data through the NHSN for at least 1 week each month and the CDC would report to CMS quarterly.

We invite public comment on this proposal.

5. Consolidated Appropriations Act and the SNF QRP

On December 27, 2020, Congress enacted the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260). Section 111(a)(3) of Division CC of the CAA amends section 1888 of the Act by adding a new paragraph (h)(12), which requires the Secretary to apply a process to validate the measures submitted under the SNF VBP and the measures and data submitted under the SNF QRP as appropriate, which may be similar to the process specified under the Hospital Inpatient Quality Reporting (IQR) Program for validating inpatient hospital measures. We plan to develop a process for validating the SNF QRP measures and data and implement this policy as soon as technically feasible. We will provide more details and seek public comment in future rulemaking. For more information on the SNF VBP please refer to section VII. of this rule.

H. Proposed Policies Regarding Public Display of Measure Data for the SNF QRP

1. Background

Section 1899B(g) of the Act requires the Secretary to establish procedures for making the SNF QRP data available to the public, including the performance of individual SNFs, after ensuring that SNFs have the opportunity to review their data prior to public display. SNF QRP measure data are currently displayed on the *Nursing homes including rehab services* website within Care Compare and the Provider Data Catalog. Both Care Compare and the Provider Data Catalog replaced Nursing Home Compare and *Data.Medicare.gov*, which were retired in December 2020. For a more detailed discussion about our policies regarding public display of SNF QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 SNF PPS final rule (81 FR 52045 through 52048).

2. Proposal to Publicly Report the Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization Measure Beginning With the FY 2023 SNF QRP

We propose public reporting for the SNF HAI measure beginning with the April 2022 Care Compare refresh or as soon as technically feasible using data collected from discharges in FY 2019 beginning October 1, 2018 through September 30, 2019. Provider preview reports would be distributed in January 2022. A SNF's HAI rates would be displayed based on 1 fiscal year of data. Since we cannot publicly report data from Q1 and Q2 of 2020 due to the PHE, we are proposing to use data collected from discharges in FY 2021 (October 1, 2020 through September 30, 2021) for public reporting of the SNF HAI measure in the October 2022 Care Compare refresh. Thereafter, the SNF HAI measure would be calculated using four quarters of FY data for the annual refresh on Care Compare. Claims-based measures are only refreshed on Care Compare annually. To ensure statistical reliability of the data, we propose assigning SNFs with fewer than 25 eligible stays during a performance period to a separate category: ''The number of resident stays is too small to report.'' Eligible stays meet the measure's denominator inclusion criteria, and we refer readers to the Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program Technical Report available at *https://www.cms.gov/files/document/snf-hai-technical-report.pdf/* for more details. If a SNF had fewer than 25 eligible stays, the SNF's performance would not be publicly reported for the measure for that performance period. We refer readers to CMS's SNF QRP Public Reporting web page for more information available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting.*

We invite public comment on this proposal for the public display of the SNF HAI measure on Care Compare.

3. Proposal to Publicly Report the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2023 SNF QRP

We propose to publicly report the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the October 2022 Care Compare refresh or as soon as technically feasible using data collected for Q4 2021 (October 1, 2021 through December 31, 2021). If finalized as proposed, a SNF's HCP COVID–19 vaccination coverage rate would be displayed based on one quarter of data. Provider preview reports would be distributed in July 2022. Thereafter, HCP COVID–19 vaccination coverage rates would be displayed based on one quarter of data updated quarterly. Subsequent to this, one additional quarter of data would be added to the measure calculation during each advancing refresh, until the point four full quarters of data is reached. Thereafter, the measure would be reported using four rolling quarters of data.

We invite public comment on this proposal for the public display of the COVID–19 Vaccination Coverage among HCP measure on Care Compare.

4. Proposals for Public Reporting of Quality Measures in the SNF QRP With Fewer Quarters Due to COVID–19 Public Health Emergency (PHE) Exemptions

a. COVID–19 Public Health Emergency Temporary Exemptions

Under the authority of section 319 of the Public Health Service Act, the Secretary of Health and Human Services declared a public health emergency (PHE) effective as of January 27, 2020. On March 13, 2020, subsequent to a presidential declaration of national emergency under the Stafford Act, the Secretary invoked section 1135(b) of the Act (42 U.S.C. 1320b-5) to waive or modify the requirements of titles XVIII, XIX, and XXI of the Act and regulations related to the PHE for COVID–19, effective as of March 1, 2020.[107] On March 27, 2020, we sent a guidance memorandum under the subject title, ''Exceptions and Extensions for Quality Reporting Requirements for Acute Care Hospitals, PPS-Exempt Cancer Hospitals, Inpatient Psychiatric Facilities, Skilled Nursing Facilities, Home Health Agencies, Hospices, Inpatient Rehabilitation Facilities, Long-Term Care Hospitals, Ambulatory Surgical Centers, Renal Dialysis Facilities, and MIPS Eligible Clinicians Affected by COVID–19'' to the Medicare Learning Network (MLN) Connects Newsletter and Other Program-Specific Listserv Recipients,[108] hereafter referred to as the March 27, 2020 CMS Guidance Memo. In that memo we granted an exception to the SNF QRP reporting requirements from Q4 2019 (October 1, 2019–December 31, 2019), Q1 2020 (January 1, 2020–March 31, 2020), and Q2 2020 (April 1, 2020–June 30, 2020). We also stated that we would not publicly report any SNF QRP data that might be greatly impacted by the exceptions from Q1 and Q2 of 2020. This exception impacted the schedule for public reporting that would have included those two quarters of data.

SNF quality measures are publicly reported on Care Compare. Care Compare uses four quarters of data for MDS assessment-based measures and eight quarters for claims-based measures. Table 28 displays the original schedule for public reporting of SNF QRP measures.[109]

TABLE 28—SNF QUARTERS IN CARE COMPARE ORIGINAL SCHEDULE FOR REFRESHES AFFECTED BY COVID–19 PEH EXEMPTIONS—ASSESSMENT AND CLAIMS BASED MEASURES

Quarter refresh	SNF quarters in original schedule for care compare
January 2021	MDS: Q2 2019—Q1 2020 (4 quarters). Claims: Q4 2017—Q3 2019 (8 quarters).
April 2021	MDS: Q3 2019—Q2 2020 (4 quarters). Claims: Q4 2017—Q3 2019 (8 quarters).
July 2021	MDS: Q4 2019—Q3 2020 (4 quarters). Claims: Q4 2017—Q3 2019 (8 quarters).
October 2021	MDS: Q1 2020—Q4 2020 (4 quarters). Claims: Q4 2018—Q3 2020 (8 quarters).
January 2022	MDS: Q2 2020—Q1 2021 (4 quarters). Claims: Q4 2018—Q3 2020 (8 quarters).
April 2022	MDS: Q3 2020—Q2 2021 (4 quarters). Claims: Q4 2018—Q3 2020 (8 quarters).
July 2022	MDS: Q4 2020—Q3 2021 (4 quarters). Claims: Q4 2018—Q3 2020 (8 quarters).
October 2022	MDS: Q1 2021—Q4 2021 (4 quarters). Claims: Q4 2019—Q3 2021 (8 quarters).
January 2023	MDS: Q2 2021—Q1 2022 (4 quarters). Claims: Q4 2019—Q3 2021 (8 quarters).
Apri1 2023	MDS: Q3 2021—Q2 2022 (4 quarters). Claims: Q4 2019—Q3 2021 (8 quarters).
July 2023	MDS: Q4 2021—Q3 2022 (4 quarters). Claims: Q4 2019—Q3 2021 (8 quarters).

During 2020, we conducted testing to inform decisions about publicly reporting data for those refreshes which include partially and/or fully exempt data (discussed below). The testing helped us develop a plan for posting data that are as up-to-date as possible and that also meet acceptable standards for public reporting. We believe that the plan allows us to provide consumers with helpful information on the quality of SNF care, while also making the necessary adjustments to accommodate the exemption provided SNFs. The following sections provide the results of our testing, and explain how we used the results to develop plans for accommodating exempt and partially-exempt data in public reporting.

b. Exempted Quarters

In the March 27, 2020 Medicare Learning Network (MLN) Newsletter on Exceptions and Extensions for Quality Reporting Program (QRP) Requirements, we stated that we would not report any PAC quality data that might be greatly impacted by the exemptions granted for Quarter 1 and Quarter 2 of 2020. Given the timing of the PHE onset, we determined that we would not use SNF MDS assessments or SNF claims from Quarter 1 and Quarter 2 of 2020 for public reporting, but that we would

[107] *https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx.*

[108] *https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf.*

[109] More information about the SNF QRP Public Reporting schedule can be found on the SNF QRP Public Reporting website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Public-Reporting.*

assess the COVID–19 PHE impact on data from Quarter 4 2019. Before proceeding with the October 2020 refresh, we conducted testing to ensure that, despite the voluntary nature of reporting for that quarter, public reporting would still meet our public reporting standards. We found the level of reporting, measured in the number of eligible stays and providers, and the reported outcomes, to be in line with levels and trends observed in FY 2018 and FY 2019. We note that Quarter 4 2019 ended before the onset of the COVID–19 pandemic in the United States. Thus, we proceeded with including these data in SNF QRP measure calculations for the October 2020 refresh.

c. Update on Data Freeze and Proposal for January 2022 Public Reporting Methodology for SNF Claims-Based and MDS Assessment-Based Measures

In addition to the January 2021 refresh, there are several other forthcoming refreshes for which the original public reporting schedules included exempted quarters of SNF QRP data. The impacted refreshes for MDS assessment and claims based measures are outlined in (Table 28). We determined that freezing the data displayed on the website with the October 2020 refresh values—that is, hold data constant after the October 2020 refresh data on the website without subsequent update—would be the most straightforward, efficient, and equitable approach for SNFs. Thus, we decided that, for as many refreshes as necessary, we would hold data constant on the website with the October 2020 data, and communicate this decision to the public.

Because October 2020 refresh data will become increasingly out-of-date and thus less useful for consumers, we analyzed whether it would be possible to use fewer quarters of data for one or more refreshes and thus reduce the number of refreshes that continue to display October 2020 data. Using fewer quarters of more up-to-date data requires that (1) a sufficient percentage of SNFs would still likely have enough assessment data to report quality measures (reportability); and (2) fewer quarters would likely produce similar measure scores for providers, with similar reliability, and thus not unfairly represent the quality of care SNFs provide during the period reported in a given refresh (reliability).

To assess these criteria, we conducted reportability and reliability analysis using 3 quarters of data in a refresh, instead of the standard 4 quarters of data for reporting assessment-based measures and using 6 quarters instead of 8 for claims-based measures. Specifically, we used historical data to calculate MDS assessment based and SNF claims based quality measures under two scenarios:

1. *Standard Public Reporting (SPR) Base Scenario:* We used four quarters of CY 2019 data as a proxy alternative for the exempted quarters in CY 2020 in order to compare results. For assessment-based measures, the quarters used in this scenario are Q1 through Q4 2019. For claims-based measures, the quarters used in this scenario are Q1 2018 through Q4 2019.

2. *COVID–19 Affected Reporting (CAR) Scenario:* We calculated SNF QRP measures using 3 quarters (Q2 2019 through Q4 2019) of SNF QRP data for assessment-based measures, and 6 quarters (Q1 2018 through Q4 2018 and Q3 2019 through Q4 2019) for claims-based measures. The CAR scenario uses the most recently available data to simulate the public health emergency reality where quarters 1 and 2 of a calendar year must be excluded from calculation. Quarterly trends in MDS assessment-based and claims based measures indicate that these measures do not exhibit substantial seasonal variation.

To assess performance in these scenarios, we calculated the reportability as the percent of SNFs meeting the case minimum for public reporting (the public reporting threshold). To test the reliability of restricting the SNFs included in the SPR Base Scenario to those included in the CAR Scenario, we performed three tests on the set of SNFs included in both scenarios. First, we evaluated measure correlation using the Pearson and Spearman correlation coefficients, which assess the alignment of SNFs' provider scores. Second, for each scenario, we conducted a split-half reliability analysis and estimated intraclass correlation (ICC) scores, where higher scores imply better internal reliability. Modest differences in ICC scores between both scenarios would suggest that using fewer quarters of data does not impact the internal reliability of the results. Third, we estimated reliability scores where a higher value indicates that measure scores are relatively consistent for patients admitted to the same SNF and variation in the measure reflects true differences across providers. To calculate the reliability results, we restricted the SNFs included in the SPR scenario to those included in the CAR scenario.

Our testing indicated that the expected impact of using fewer quarters of data on reportability and reliability of MDS assessment-based and claims based measures is acceptable.

We are proposing to use the CAR scenario as the approach for the following affected refreshes for MDS assessment-based measures, the affected refresh is the January 2022 refresh; for claims-based measures, the affected refreshes occur from January 2022 through July 2023. For the earlier four affected refreshes (January, April, July, and October 2021), we decided to hold constant the Care Compare website with October 2020 data. We communicated this decision in a Public Reporting Tip Sheet, which is located at *https://www.cms.gov/files/document/snfqrp-covid19prtipsheet-october2020.pdf.*

Our proposal of the CAR approach for the affected refreshes would allow us to begin displaying more recent data in January 2022, rather than continue displaying October 2020 data (Q1 2019 through Q4 2019 for assessment-based measures, Q4 2017 through Q3 2019 for claims-based measures). We believe that resuming public reporting starting in January 2022 with fewer quarters of data can assist consumers by providing more recent quality data as well as more actionable data for SNF providers. Our testing results indicate we can achieve these positive impacts with acceptable changes in reportability and reliability. Table 29 summarizes the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for assessment-based measures. Tables 30 and 31 summarize the revised schedule (that is, frozen data) and the proposed schedule (that is, using fewer quarters in the affected refreshes) for claims-based measures.

We invite public comment on the proposal to use the CAR scenario to publicly report SNF measures for the January 2022–July 2023 refreshes.

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TABLE 29: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for SNF MDS Assessment-based QMs

Quarter Refresh	MDS Assessment Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
October 2020	Q1 2019 – Q4 2019 (4)
January 2021	Q1 2019 – Q4 2019 (4)
April 2021	Q1 2019 – Q4 2019 (4)
July 2021	Q1 2019 – Q4 2019 (4)
October 2021	Q1 2019 – Q4 2019 (4)
January 2022	Q3 2020 – Q1 2021 (3)
April 2022	Q3 2020 – Q2 2021 (4)* *Normal reporting resumes with 4 quarters of data

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 30: Revised and Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for SNF Claims-based QMs

Quarter Refresh	Claims-based Quarters in Revised/Proposed Schedule for Care Compare (number of quarters)
October 2020	Q4 2017 – Q3 2019 (8)
January 2021	Q4 2017 – Q3 2019 (8)
April 2021	Q4 2017 – Q3 2019 (8)
July 2021	Q4 2017 – Q3 2019 (8)
October 2021	Q4 2017 – Q3 2019 (8)
January 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
April 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
July 2022	Q4 2018 – Q4 2019, Q3 2020 (6)
October 2022	Q4 2019, Q3 2020 – Q3 2021 (6)
January 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
April 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
July 2023	Q4 2019, Q3 2020 – Q3 2021 (6)
October 2023	Q4 2020 – Q3 2022 (8)* *Normal reporting resumes with 8 quarters of data

Note: The shaded cells represent data held constant due to PHE related to COVID-19.

TABLE 31: Proposed Schedule for Refreshes Affected by COVID-19 PHE Exemptions for the SNF HAI Measure

Quarter Refresh	Claims-based Quarters in Proposed Schedule for Care Compare (number of quarters)
April 2022	Q4 2018 – Q3 2019 (4)
July 2022	Q4 2018 – Q3 2019 (4)
October 2022	Q4 2020 - Q3 2021 (4) *Normal reporting resumes for claims-based measures refreshed annually

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VII. Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program

A. Background

Section 215(b) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) authorized the SNF VBP Program (the ''Program'') by adding section 1888(h) to the Act. As a prerequisite to implementing the SNF VBP Program, in the FY 2016 SNF PPS final rule (80 FR 46409 through 46426), we adopted an all-cause, all-condition hospital readmission measure, as required by section 1888(g)(1) of the Act, and discussed other policies to implement the Program such as performance standards, the performance period and baseline period, and scoring. SNF VBP Program policies have been codified in our regulations at § 413.338. For additional background information on the SNF VBP Program, including an overview of the SNF VBP Report to Congress and a summary of the Program's statutory requirements, we refer readers to the following prior final rules:

- In the FY 2017 SNF PPS final rule (81 FR 51986 through 52009), we adopted an all-condition, risk-adjusted potentially preventable hospital readmission measure for SNFs, as required by section 1888(g)(2) of the Act, adopted policies on performance standards, performance scoring, and sought comment on an exchange function methodology to translate SNF performance scores into value-based incentive payments, among other topics.
- In the FY 2018 SNF PPS final rule (82 FR 36608 through 36623), we adopted additional policies for the Program, including an exchange function methodology for disbursing value-based incentive payments.
- In the FY 2019 SNF PPS final rule (83 FR 39272 through 39282), we adopted more policies for the Program, including a scoring adjustment for low-volume facilities.
- In the FY 2020 SNF PPS final rule (84 FR 38820 through 38825), we adopted additional policies for the Program, including a change to our public reporting policy and an update to the deadline for the Phase One Review and Correction process. We also adopted a data suppression policy for low-volume SNFs.
- In the FY 2021 SNF PPS final rule (85 FR 47624 through 47627), we amended regulatory text definitions at § 413.338(a)(9) and (11) to reflect the definition of Performance Standards and the updated Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure name, respectively. We also updated the Phase One Review and Correction deadline and codified that update at § 413.338(e)(1). Additionally, we codified the data suppression policy for low-volume SNFs at § 413.338(e)(3)(i), (ii), and (iii) and amended § 413.338(e)(3) to reflect that SNF performance information will be publicly reported on the Nursing Home Compare website and/or successor website (84 FR 38823 through 38824) which since December 2020 is the Provider Data Catalogue website (*https://data.cms.gov/provider-data/*).

The SNF VBP Program applies to freestanding SNFs, SNFs affiliated with acute care facilities, and all non-CAH swing-bed rural hospitals. Section 1888(h)(1)(B) of the Act requires that the SNF VBP Program apply to payments for services furnished on or after October 1, 2018. We believe the implementation of the SNF VBP Program is an important step towards transforming how payment is made for care, moving increasingly towards rewarding better value, outcomes, and innovations instead of merely rewarding volume.

B. Measures

For background on the measures we have adopted for the SNF VBP Program, we refer readers to the FY 2016 SNF PPS final rule (80 FR 46419), where we finalized the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) (NQF #2510) that we are currently using for the SNF VBP Program. We also refer readers to the FY 2017 SNF PPS final rule (81 FR 51987 through 51995), where we finalized the Skilled Nursing Facility 30-Day Potentially Preventable Readmission Measure (SNFPPR) that we will use for the SNF VBP Program instead of the SNFRM as soon as practicable, as required by statute. The SNFPPR measure's name is now ''Skilled Nursing Facility Potentially Preventable Readmissions after Hospital Discharge measure'' (§ 413.338(a)(11)). We intend to submit the SNFPPR measure for NQF endorsement review during the Fall 2021 cycle, and to assess transition timing of the SNFPPR measure to the SNF VBP Program after NQF endorsement review is complete.

1. Proposed Flexibilities for the SNF VBP Program in Response to the Public Health Emergency Due to COVID–19

In previous rules, we have identified the need for flexibility in our quality programs to account for the impact of changing conditions that are beyond participating facilities' or practitioners' control. We identified this need because we would like to ensure that participants in our programs are not affected negatively when their quality performance suffers not due to the care provided, but due to external factors.

A significant example of the type of external factor that may affect quality measurement is the COVID–19 public health emergency (PHE), which has had, and continues to have, significant and ongoing effects on the provision of medical care in the country and around the world. The COVID–19 pandemic and associated PHE has impeded effective quality measurement in many ways. Changes to clinical practices to incorporate safety protocols for medical personnel and patients, as well as unpredicted changes in the number of stays and facility-level case mixes, have affected the data that SNFs report under the SNF VBP Program and the resulting measure calculations. CMS is currently considering whether the SNF readmission measure specifications should be updated to account for changes in SNF admission and/or hospital readmission patterns that we have observed during the PHE. Additionally, because COVID–19 prevalence is not identical across the country, facilities located in different areas have been affected differently at different times throughout the pandemic. Under those circumstances, we remain concerned that the SNF readmission measure scores are distorted, which would result in skewed payment incentives and inequitable payments, particularly for SNFs that have treated more COVID–19 patients than others.

It is not our intention to penalize SNFs based on measure scores that we believe are distorted by the COVID–19 pandemic, and are thus not reflective of the quality of care that the measure in the SNF VBP Program was designed to assess. As discussed above, the COVID–19 pandemic has had, and continues to have, significant and enduring effects on health care systems around the world, and affects care decisions, including readmissions to the hospital as measured by the SNF VBP Program. As a result of the PHE, SNFs could provide care to their patients that meets the underlying clinical standard but results in worse measured performance, and by extension, lower incentive payments in the SNF VBP Program. Additionally, because COVID–19 prevalence has not been identical across the country, SNFs located in different regions have been affected differently during the PHE. As a result, we are concerned that regional differences in COVID–19 prevalence during the revised performance period for the FY 2022 SNF VBP Program, which includes one quarter of data

during the pandemic (July 1, 2020 through September 30, 2020), have directly affected SNF readmission measure scores for the FY 2022 SNF VBP program year. Although these regional differences in COVID–19 prevalence rates do not reflect differences in the quality of care furnished by SNFs, they directly affect the value-based incentive payments that these SNFs are eligible to receive and could result in an unfair and inequitable distribution of those incentives. These inequities could be especially pronounced for SNFs that have treated a large number of COVID–19 patients.

Therefore, we are proposing to adopt a policy for the duration of the PHE for COVID–19 that would enable us to suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments in the SNF VBP Program if we determine that circumstances caused by the PHE for COVID–19 have affected the measure and the resulting performance scores significantly. Under this proposed policy, if we determine that the suppression of the SNF readmission measure is warranted for a SNF VBP program year, we would propose to calculate the SNF readmission measure rates for that program year but then suppress the use of those rates to generate performance scores, rank SNFs, and generate value-based incentive payment percentages based on those performance scores. We would instead assign each eligible SNF's performance score of zero for the program year to mitigate the effect that the distorted measure results would otherwise have on SNF's performance scores and incentive payment multipliers. We would also reduce each eligible SNF's adjusted Federal per diem rate by the applicable percent (2 percent) and then further adjust the resulting amounts by a value-based incentive payment amount equal to 60 percent of the total reduction. Those SNFs subject to the Low-Volume Adjustment policy would receive 100 percent of their 2 percent withhold per the policy previously finalized in the FY 2020 SNF PPS final rule (84 FR 38823 through 38824). We would also provide each SNF with its SNF readmission measure rate in confidential feedback reports so that the SNF is aware of the observed changes to its measure rates. We would also publicly report the FY 2022 SNF readmission measure rates with appropriate caveats noting the limitations of the data due to the PHE for COVID–19.

In developing this proposed policy, we considered what circumstances caused by the PHE for COVID–19 would affect a quality measure significantly enough to warrant its suppression in a value-based purchasing program. We believe that a significant deviation in measured performance that can be reasonably attributed to the PHE for COVID–19 is a significant indicator of changes in clinical conditions that affect quality measurement. Similarly, we believe that a measure may be focused on a clinical topic or subject that is proximal to the disease, pathogen, or other health impacts of the PHE. As has been the case during the COVID–19 PHE, we believe that rapid or unprecedented changes in clinical guidelines and care delivery, potentially including appropriate treatments, drugs, or other protocols, may affect quality measurement significantly and should not be attributed to the participating facility positively or negatively. We also note that scientific understanding of a particular disease or pathogen may evolve quickly during an emergency, especially in cases of new disease or conditions. Finally, we believe that, as evidenced during the COVID–19 PHE, national or regional shortages or changes in health care personnel, medical supplies, equipment, diagnostic tools, and patient case volumes or facility-level case mix may result in significant distortions to quality measurement.

Based on these considerations, we developed a number of Measure Suppression Factors that we believe should guide our determination of whether to propose to suppress the SNF readmission measure for one or more program years that overlap with the PHE for COVID–19. We are proposing to adopt these Measure Suppression Factors for use in the SNF VBP and, for consistency, the following other value-based purchasing programs: Hospital Value-Based Purchasing Program, Hospital Readmissions Reduction Program, HAC Reduction Program, and End-Stage Renal Disease Quality Incentive Program. We believe that these Measure Suppression Factors will help us evaluate the SNF readmission measure in the SNF VBP program and that their adoption in the other value-based purchasing programs noted above will help ensure consistency in our measure evaluations across programs. The proposed Measure Suppression Factors are:

(1) Significant deviation in national performance on the measure during the PHE for COVID–19, which could be significantly better or significantly worse compared to historical performance during the immediately preceding program years.

(2) Clinical proximity of the measure's focus to the relevant disease, pathogen, or health impacts of the PHE for COVID–19.

(3) Rapid or unprecedented changes in:

- Clinical guidelines, care delivery or practice, treatments, drugs, or related protocols, or equipment or diagnostic tools or materials; or
- The generally accepted scientific understanding of the nature or biological pathway of the disease or pathogen, particularly for a novel disease or pathogen of unknown origin.

(4) Significant national shortages or rapid or unprecedented changes in:

- Healthcare personnel;
- Medical supplies, equipment, or diagnostic tools or materials; or
- Patient case volumes or facility-level case mix.

We also considered alternatives to this proposed policy that could also fulfill our objective to not hold facilities accountable for measure results that are distorted due to the PHE for COVID–19. As noted above, the country continues to grapple with the effects of the COVID–19 PHE, and in March 2020, we issued a nationwide, blanket Extraordinary Circumstances Exception (ECE) for all hospitals and other facilities participating in our quality reporting and value-based purchasing programs in response to the PHE for COVID–19. This blanket ECE excepted all data reporting requirements for Q1 and Q2 2020 data. For claims-based measures, we also stated that we would exclude all qualifying Q1 and Q2 2020 claims from our measure calculations. We considered extending the blanket ECE that we issued for Q1 and Q2 2020 to also include Q3 2020 data. However, this option would result in less than 12 months of data being used to calculate the single readmissions measure in the Program for multiple Program years, which we do not believe would provide an accurate assessment of the quality of care provided in SNFs. This option would also leave no comprehensive data available for us to provide confidential performance feedback to providers nor for monitoring and to inform decision-making for potential future programmatic changes, particularly as the PHE is extended.

We view this measure suppression proposal as a necessity to ensure that the SNF VBP program does not reward or penalize facilities based on factors that the SNF readmission measure was not designed to accommodate. We intend for this proposed policy to provide short-term relief to SNFs when we have determined that one or more of the Measure Suppression Factors

warrants the suppression of the SNF readmission measure.

We invite public comments on this proposal for the adoption of a measure suppression policy for the SNF VBP Program for the duration of the PHE for COVID–19, and also on the proposed Measure Suppression Factors that we developed for purposes of this proposed policy.

We are also inviting comment on whether we should consider adopting a measure suppression policy that would apply in a future national PHE, and if so, whether under such a policy, we should have the flexibility to suppress quality measures without specifically proposing to do so in rulemaking. We also request comment on whether we should in future years consider adopting any form of regional adjustment for the proposed measure suppression policy that could take into account any disparate effects of circumstances affecting hospitals around the country that would prompt us to suppress a measure. For example, COVID–19 affected different regions of the country at different rates depending on factors like time of year, geographic density, state and local policies, and health care system capacity. In future years and for future PHEs, should they arise, we also request commenters' feedback on whether we should, rather than suppress a measure completely, consider a suppression policy with more granular effects based on our assessment of the geographic effects of the circumstances, and if so, how region-based measure suppression could be accounted for within the program's scoring methodology.

2. Proposal To Suppress the SNFRM for the FY 2022 SNF VBP Program Year

In this proposed rule, we are proposing to suppress the SNFRM for the FY 2022 SNF VBP Program Year under proposed Measure Suppression Factor: (4) Significant national shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case mix.

In response to the PHE for COVID–19, we granted an extraordinary circumstance exemption (ECE) for SNFs participating in the SNF VBP Program. Under the ECE, SNF qualifying claims for the period January 1, 2020–June 30, 2020 are excepted from the calculation of the SNFRM. Because this ECE excepted data for 6 months of the performance period that we had previously finalized for the FY 2022 SNF VBP program year (84 FR 38822), we updated the performance period for that program year in the ''Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments, and Patient Protection and Affordable Care Act: Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency'' interim final rule with comment (''the September 2nd IFC'') (85 FR 54820). Specifically, we finalized that the new performance period for the FY 2022 SNF VBP Program year would be April 1, 2019–December 31, 2019 and July 1, 2020–September 30, 2020 because we believed that this period, which combined 9 months of data prior to the start of the PHE for COVID–19 and 3 months of data after the end of the ECE, would provide sufficiently reliable data for evaluating SNFs for the FY 2022 SNF VBP Program. However, analyses conducted by our contractor since the publication of the September 2nd IFC have found that when July–September 2020 SNF data are compared with July–September 2019 SNF data, the July–September 2020 SNF data showed 25 percent fewer SNF admissions and 26 percent fewer readmissions from a SNF to a hospital. These impacts have affected the reliability of the SNFRM. Generally speaking, the SNFRM's reliability decreases as the sample size and measured outcome (that is, readmissions) decrease. A drop of 25 percent in SNF admissions and 26 percent in readmissions to the hospital from July–September 2020 has significantly reduced the sample size needed to calculate both the measure cohort and outcome for the FY 2022 SNF VBP, thus jeopardizing the measure reliability. Our contractor's analysis using FY 2019 data showed that such changes may lead to a 15 percent decrease in the measure reliability, assessed by the intra-class correlation coefficient (ICC). In addition, the current risk-adjustment model does not factor in COVID–19 or the fact that SNFs are treating different types of patients as a result of the COVID–19 PHE. Nearly 10 percent of SNF residents in July–September 2020 had a current or prior diagnosis of COVID–19, with uneven regional impacts. The SNFRM does not adjust for COVID–19 in the risk adjustment methodology, as the measure was developed before the pandemic. As a result, risk-adjusted rates, which compare SNFs to each other nationally, are likely to reflect variation in COVID–19 prevalence rather than variation in quality of care. We do not believe that assessing SNFs on a quality measure affected significantly by the varied regional response to the COVID–19 PHE presents a clear picture of the quality of care provided by an individual SNF. The data also demonstrated other important changes in SNF patient case-mix during the PHE for COVID–19, including an 18 percent increase in dual-eligible residents and a 9 percent increase in African-American SNF residents at the facility level. They have been disproportionately impacted by COVID, both in terms of morbidity and mortality. We are currently conducting analyses to determine whether and how the SNFRM specifications may need to be updated to account for SNF residents with a primary or secondary diagnosis of COVID–19 for future program years. We also plan to conduct such analysis for the SNFPPR measure.

We considered whether we could propose to remove the July 1, 2020–September 30, 2020 data from the updated performance period for the FY 2022 SNF VBP program year and calculate the SNFRM using a 9-month performance period (April 1, 2019–December 31, 2019). To determine whether the measure would be reliable using data during this period, which would be closer to 8 months once we remove all SNF stays whose 30-day readmission risk-window extended to or after January 1, 2020, we performed reliability analyses using a formula that relates the reliability of a measure to its intraclass correlation (ICC), and found that an estimate of reliability using all 12 combinations of potential 8-month data periods from FY 2019 (that is, October through May, November through June, and so on) [110] produces an average reliability estimate of 0.367, which is lower than our generally accepted minimum reliability threshold of 0.40.

We also considered substituting the July 1, 2020–September 30, 2020 period with an alternate data period; however, we are limited operationally in terms of which data may be used. Using data from further in the future would cause a delay in the calculation and dissemination of results for the FY 2022 Program. Such a delay could require us to make adjustments to the otherwise applicable Federal per diem rate paid to SNFs in FY 2022 on a delayed basis, which would be an extremely burdensome process for the MACs and a potentially confusing process for SNFs. While using older data is feasible, and we recognize that we adopted a performance period in the September 2nd IFC that duplicated the use of data from a previous performance period, our

[110] We assessed multiple 8-month data periods and averaged the reliability results to obtain a complete understanding of reliability across FY 2019, the most recent full year of production data available for analysis, and avoid potential issues caused by seasonality.

preference is to use as much new data as possible to assess SNF performance each year and to avoid, where feasible, using the same data as a performance period in multiple program years. Further revising the FY 2022 Program performance period to include older data would create a substantial overlap with the FY 2021 Program's performance period. Such a significant overlap would result in SNFs receiving payments in FY 2022 based largely on the same performance used to assess SNFs for the FY 2021 program year. Using over 80 percent of the same data twice as a performance period could result in some SNFs being penalized (or receiving a bonus) twice for nearly the same performance.

Therefore, due to concerns about the validity of the measure when calculated as currently specified on data during the PHE given the significant changes in SNF patient case volume and facility-level case mix described above, and lacking any viable alternatives, we are proposing to suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments in the FY 2022 program year, under the proposed Measure Suppression Factor (4) Significant national or regional shortages or rapid or unprecedented changes in: (iii) Patient case volumes or facility-level case mix.

Under this proposed suppression policy, for all SNFs participating in the FY 2022 SNF VBP program, we will use the previously finalized performance period and baseline period to calculate each SNF's RSRR for the SNFRM. Then, we would suppress the use of SNF readmission measure data for purposes of scoring and payment adjustments. Specifically, we are proposing to change the scoring methodology to assign all SNFs a performance score of zero in the FY 2022 Program year. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We would then apply the Low-Volume Adjustment policy as previously finalized in the FY 2020 SNF PPS final rule (84 FR 38823 through 38824). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier. SNFs will not be ranked for the FY 2022 SNF VBP program.

Under this proposal we would reduce each participating SNF's adjusted Federal per diem rate for FY 2022 by 2 percentage points and award each participating SNF 60 percent of that 2 percent withhold, resulting in a 1.2 percent payback for the FY 2022 program year. We believe this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all qualifying SNFs is the most equitable way to reduce the impact of the withhold in light of our proposal to award a performance score of zero to all SNFs. Those SNFs subject to the Low-Volume Adjustment policy would receive 100 percent of their 2 percent withhold per the previously finalized policy increasing the overall payback percentage to an estimated 62.9 percent.

Further, we propose to provide quarterly confidential feedback reports to SNFs and publicly report the SNFRM rates for the FY 2022 SNF VBP Program year. However, we will make clear in the public presentation of those data that the measure has been suppressed for purposes of scoring and payment adjustments because of the effects of the PHE for COVID–19 on the data used to calculate the measure. We propose to codify this policy at § 413.338(g).

We invite public comment on this proposal.

3. Proposed Revision to the SNFRM Risk Adjustment Look-Back Period for the FY 2023 SNF VBP Program

In the FY 2021 SNF PPS final rule (85 FR 47624), we finalized the FY 2023 Program performance period as FY 2021 (October 1, 2020–September 30, 2021). In the FY 2016 SNF PPS final rule (80 FR 46418), we finalized that the risk adjustment model would account for certain risk-factors within 365 days prior to the discharge from the hospital to the SNF (a 365-day lookback period). Under the COVID–19 ECE, SNF qualifying claims for the period January 1, 2020–June 30, 2020 are excepted from the calculation of the SNFRM; using FY 2021 data this results in at least 3 months of lookback being available for all SNF stays included in the measure without extending into or beyond June 30, 2020. Here, we propose instead a 90-day lookback period for risk adjustment in the FY 2023 performance period (FY 2021) only. Using a 90-day risk-adjustment period will allow us to use the most recent claims available for risk-adjustment, and an identical risk-adjustment lookback period for all stays included in the measure. It also allows us to avoid combining data from both prior to and during the COVID–19 PHE in the risk-adjustment lookback period, which would be necessary if we attempted to maintain a 12-month look-back period due to the COVID–19 ECE. Using a 90-day lookback period for risk adjustment will allow us to look back 90 days prior to the discharge from the hospital to the SNF for each SNF stay. Analyses conducted on FY 2019 performance data found that when compared to the 365-day lookback period traditionally used, a 90-day lookback period resulted in similar model performance (that is, the C-statistic was nearly identical). We are also considering similarly reducing the risk-adjustment lookback period for the applicable FY 2023 program baseline year which would align the risk-adjustment lookback period for the baseline and performance years in the FY 2023 program; we invite comments on this consideration.

We invite public comment on the proposed updates to the risk adjustment look-back period for the FY 2023 Performance Period.

4. Request for Comments on Potential Future Measures for the SNF VBP Program

On December 27, 2020, Congress enacted the Consolidated Appropriations Act, 2021 (CAA) (Pub. L. 116–260). Section 111(a)(1) of Division CC of the CAA amends section 1888(h)(1) of the Act to, with respect to payments for services furnished on or after October 1, 2022, preclude the SNF VBP from applying to a SNF for which there are not a minimum number (as determined by the Secretary) of cases for the measures that apply to the facility for the performance period for the applicable fiscal year, or measures that apply to the facility for the performance period for the applicable fiscal year. Section 111(a)(2) of the CAA amended section 1888(h)(2)(A) of the Act to, with respect to payments for services furnished on or after October 1, 2023, require the Secretary to apply the readmission measure specified under section 1888(g)(1) of the Act, and allow the Secretary to apply up to 9 additional measures determined appropriate, which may include measures of functional status, patient safety, care coordination, or patient experience. To the extent that the Secretary decides to apply additional measures, section 1888(h)(2)(A)(ii) of the Act, as amended by section 111(a)(2)(C) of the CAA, requires the Secretary to consider and apply, as appropriate, quality measures specified under section 1899B(c)(1) of the Act. Finally, section 111(a)(3) of the CAA amended section 1888(h) of the Act by adding a new paragraph (12), which requires that the Secretary apply a process to validate the measures and data submitted under the SNF VBP and the SNF QRP, as appropriate, which may be similar to the process specified under the Hospital Inpatient Quality Reporting (IQR) Program for validating

inpatient hospital measures. In this proposed rule, we are seeking input from stakeholders regarding which measures we should consider adding to the SNF VBP Program. We intend to use future rulemaking to address these new statutory requirements.

Currently, the SNF VBP Program includes only a single quality measure, the SNFRM, which we intend to transition to the SNFPPR measure as soon as practicable. Both the SNFRM and SNFPPR assess the risk-adjusted rate of readmissions to hospitals, for SNF residents within 30 days of discharge from a prior hospital stay. Consistent with amended section 1888(h)(2)(A)(ii) of the Act, in considering which measures might be appropriate to add to the SNF VBP Program, we are considering additional clinical topics such as measures of functional status, patient safety, care coordination, and patient experience, as well as measures on those topics that are utilized in the SNF Quality Reporting Program (QRP). For more information about the SNF QRP measures, please visit: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Skilled-Nursing-Facility-Quality-Reporting-Program/SNF-Quality-Reporting-Program-Measures-and-Technical-Information.*

We are also considering measures on clinical topics that are not included in the SNF QRP's measure set because we believe that other clinical topics would be helpful to our efforts to robustly assess the quality of care furnished by SNFs.

In expanding the SNF VBP measure set, we are also considering measures that we already require for Long-Term Care Facilities (LTCFs), which include both SNFs and nursing facilities (NFs), to collect and report under other initiatives. Approximately 94 percent of LTCFs are dually certified as both a SNF and NF (Provider Data Catalog Nursing Homes and Rehab Services Provider Information File January 2021) (*https://data.cms.gov/provider-data/dataset/4pq5-n9py*). The vast majority of LTCF residents are also Medicare beneficiaries, regardless of whether they are in a Medicare Part A SNF stay, because they are enrolled in Medicare Part B and receive Medicare coverage of certain services provided by the LTCF even if they are a long-term care resident. Therefore, we believe that expanding the SNF VBP measure set to assess the quality of care that SNFs provide to all residents of the facility, regardless of payer, would best represent the quality of care provided to all Medicare beneficiaries in the facility. We are requesting public comment on whether the measures in an expanded SNF VBP measure set should require SNFs to collect data on all residents in the facility, regardless of payer.

We have identified the measures listed in Table 31 as measures we could add to the SNF VBP Program measure set, and we seek comment on those measures, including which of those measures would be best suited for the program. We also seek public comment on any measures or measure concepts that are not listed in Table 31 that stakeholders believe we should consider for the SNF VBP Program. In considering an initial set of measures with which SNFs should largely be familiar (through the SNF QRP, 5-Star Rating Program and/or the Nursing Home Quality Initiative (NHQI)), we believe we can implement a measure set that would impose minimal additional burden on SNFs.

TABLE 31—QUALITY MEASURES UNDER CONSIDERATION FOR AN EXPANDED SKILLED NURSING FACILITY VALUE-BASED PURCHASING PROGRAM

Meaningful measure area	NQF	Quality measure
Minimum Data Set		
Functional Outcomes	A2635	Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients.*
Functional Outcomes	A2636	Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients.*
Preventable Healthcare Harm	0674	Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).**
Preventable Healthcare Harm	0679	Percent of High Risk Residents with Pressure Ulcers (Long Stay).**
Functional Outcomes	N/A	Percent of Residents Whose Ability to Move Independently Worsened (Long Stay).**
Functional Outcomes	N/A	Percent of Residents Whose Need for Help with Activities of Daily Living Has Increased (Long Stay).**
Transfer of Health Information and Interoperability.	N/A	Transfer of Health Information to the Provider–Post Acute Care.*
Medication Management	N/A	Percentage of Long-Stay Residents who got an Antipsychotic Medication.**
Medicare Fee-For-Service Claims Based Measures		
Community Engagement	3481	Discharge to Community Measure-Post Acute Care Skilled Nursing Facility Quality Reporting Program.*
Patient-focused Episode of Care	N/A	Medicare Spending per Beneficiary (MSPB)-Post Acute Care Skilled Nursing Facility Quality Reporting Program.*
Healthcare-Associated Infections	N/A	Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization Measure.~
Admissions and Readmissions to Hospitals	N/A	Number of hospitalizations per 1,000 long-stay resident days (Long Stay).**
Patient-Reported Outcome-Based Performance Measure		
Functional Outcomes	N/A	Patient-Reported Outcomes Measurement Information System [PROMIS]-PROMIS Global Health, Physical.

TABLE 31—QUALITY MEASURES UNDER CONSIDERATION FOR AN EXPANDED SKILLED NURSING FACILITY VALUE-BASED PURCHASING PROGRAM—Continued

Meaningful measure area	NQF	Quality measure
Survey Questionnaire (similar to Consumer Assessment of Healthcare Providers and Systems (CAHPS))		
Patient's Experience of Care	2614	CoreQ: Short Stay Discharge Measure.
Payroll Based Journal		
N/A	N/A	Nurse staffing hours per resident day: Registered Nurse (RN) hours per resident per day; Total nurse staffing (including RN, licensed practical nurse (LPN), and nurse aide) hours per resident per day.**

* Measures adopted in the SNF Quality Reporting Program (QRP).
** ** These measures are reported on the Nursing Home Care Compare website (*https://www.medicare.gov/care-compare/*).
~ Measure proposed in section VII.C.1 of this proposed rule for adoption in the SNF QRP.

In addition to the staffing measures listed in Table 31 that focus on nurse staffing hours per resident day and that are currently reported on the Nursing Home Care Compare website, we are also interested in measures that focus on staff turnover. We have been developing measures of staff turnover, as required by section 1128I(g) of the Act, with the goal of making the information publicly available. Through our implementation of the Payroll-Based Journal (PBJ) staffing data collection program, we have indicated that we will be reporting rates of turnover in the future (for more information on this program, see CMS memorandum QSO–18–17–NH [111]). As we plan to report staff turnover information in the near future, we are also seeking comment on inclusion of these measures in the SNF VBP Program.

We are also considering two patient-reported measures, as listed in Table 31, to assess residents' views of their healthcare.

The CoreQ: Short Stay Discharge Measure calculates the percentage of individuals discharged in a 6-month time period from a SNF, within 100 days of admission, who are satisfied with their SNF stay. This patient reported outcome measure is based on the CoreQ: Short Stay Discharge questionnaire that utilizes four items: (1) In recommending this facility to your friends and family, how would you rate it overall; (2) Overall, how would you rate the staff; (3) How would you rate the care you receive; (4) How would you rate how well your discharge needs were met. For additional information about the CoreQ: Short Stay Discharge Measure, please visit *https://cmit.cms.gov/CMIT_public/ViewMeasure?MeasureId=3436.*

[111] *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-17-NH.pdf.*

We welcome public comment on future measures for the SNF VBP Program, and on whether the measures in an expanded SNF VBP measure set should require SNFs to collect data on all residents in the facility, regardless of payer.

C. SNF VBP Performance Period and Baseline Period

1. Background

We refer readers to the FY 2016 SNF PPS final rule (80 FR 46422) for a discussion of our considerations for determining performance periods under the SNF VBP Program. In the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), we adopted a policy whereby we will automatically adopt the performance period and baseline period for a SNF VBP program year by advancing the performance period and baseline period by 1 year from the previous program year.

2. Revised Performance Period for the FY 2022 SNF VBP Program

In the September 2nd IFC, we updated the performance period for the FY 2022 SNF VBP Program to April 1, 2019 through December 31, 2019 and July 1, 2020 through September 30, 2020. We also noted that the baseline period of the FY 2022 Program had not been impacted by the PHE for COVID–19 and will remain as FY 2018 (October 1, 2017 through September 30, 2018), and the FY 2022 Program performance standards included in the FY 2020 final rule (84 FR 38822 through 38823) will remain as finalized.

However, as noted in section VII.B.3. of this proposed rule, there are concerns about the validity of the measure when calculated as currently specified on data during the PHE (specifically, July 1, 2020 through September 30, 2020) given the significant changes in SNF patient case volume and facility-level case mix described above. Therefore, we are proposing to suppress the SNFRM for the FY 2022 program year. We will calculate each SNF's RSRR for the SNFRM. Then, we would change the scoring methodology to assign all SNFs a performance score of zero. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We would then apply the Low-Volume Adjustment policy as previously finalized in the FY 2020 SNF PPS final rule (84 FR 38823 through 38824). That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier. We will continue to provide quarterly confidential feedback reports to facilities and publicly report based on the usable data from the previously finalized performance period (April 1, 2019 through December 31, 2019) and the previously finalized baseline period (FY 2018).

3. Performance Period for the FY 2023 SNF VBP Program

In the FY 2021 SNF PPS final rule (85 FR 47624), we finalized that the Performance Period for the FY 2023 program year would be October 1, 2020–September 30, 2021 (FY 2021) and the baseline would be FY 2019 (October 1, 2018–September 30, 2019). We are not proposing any updates to the performance period and baseline period previously finalized for FY 2023.

We also considered alternatives to the previously finalized performance period for FY 2023. We considered modifying the performance period for the FY 2023 program year to Calendar Year 2021 (January 1, 2021–December 31, 2021). However, CY 2021 data are available later than FY 2021 data, and would likely result in a delay calculating SNFRM scores for SNFs and a subsequent delay in the application of

payment incentives for the FY 2023 program year.

We acknowledge that the COVID–19 PHE extends into both performance period options. We believe that following the completion of testing, SNF readmission measure specifications may account for changes in SNF admission and/or hospital readmission patterns that we have observed during the PHE as noted above.

We invite public comment on this alternative to the previously finalized Performance Period for the FY 2023 SNF VBP program.

4. Performance Period and Baseline Period for the FY 2024 SNF VBP Program

Under the policy finalized in the FY 2019 SNF PPS final rule (83 FR 39277 through 39278), for the FY 2024 program year, the performance period would be FY 2022 and the baseline period would be FY 2020. However, under the ECE, SNF qualifying claims for a 6-month period in FY 2020 (January 1, 2020–June 30, 2020) are excepted from the calculation of the SNFRM, which means that we will not have a full year of data to calculate the SNFRM for the FY 2020 baseline period. Moreover, as described in more detail in section VII.B.3 above, we are proposing to suppress the SNFRM for the FY 2022 program year, in part because there are concerns about the validity of the measure when calculated as currently specified on data during the PHE (specifically, July 1, 2020 through September 30, 2020) given the significant changes in SNF patient case volume and facility-level case mix described above. As the SNF VBP Program uses only a single measure calculated on 1 year of data and uses each year of data first as a performance period and then later on as a baseline period in the Program, the removal of 9 months of data in light of the COVID–19 PHE as described above will necessarily result in data being used more than once in the Program. Therefore, to ensure enough data are available to reliably calculate the SNFRM, we are proposing FY 2019 data be used for the baseline period for the FY 2024 program year. We also considered using FY 2021, which will be the baseline period for the FY 2025 program year under our current policy. However, it is operationally infeasible for us to calculate the baseline for the FY 2024 program year using FY 2021 data in time to establish the performance standards for that program year at least 60 days prior to the start of the performance period, as required under section 1888(h)(3)(C) of the Act.

We invite public comment on this proposal.

D. Performance Standards

1. Background

We refer readers to the FY 2017 SNF PPS final rule (81 FR 51995 through 51998) for a summary of the statutory provisions governing performance standards under the SNF VBP Program and our finalized performance standards policy. We adopted the final numerical values for the FY 2022 performance standards in the FY 2020 SNF PPS final rule (84 FR 38822), and adopted the final numerical values for the FY 2023 performance standards in the FY 2021 SNF PPS final rule (85 FR 47625). We also adopted a policy allowing us to correct the numerical values of the performance standards in the FY 2019 SNF PPS final rule (83 FR 39276 through 39277).

We are not proposing any changes to these performance standard policies in this proposed rule.

2. SNF VBP Performance Standards Correction Policy

In the FY 2019 SNF PPS final rule (83 FR 39276 through 39277), we finalized a policy to correct numerical values of performance standards for a program year in cases of errors. We also finalized that we will only update the numerical values for a program year one time, even if we identify a second error, because we believe that a one-time correction will allow us to incorporate new information into the calculations without subjecting SNFs to multiple updates. We stated that any update we make to the numerical values based on a calculation error will be announced via the CMS website, listservs, and other available channels to ensure that SNFs are made fully aware of the update. In the FY 2021 SNF PPS final rule (85 FR 47625), we amended the definition of ''Performance standards'' at § 413.338(a)(9), consistent with these policies finalized in the FY 2019 SNF PPS final rule, to reflect our ability to update the numerical values of performance standards if we determine there is an error that affects the achievement threshold or benchmark. We are not proposing any changes to the performance standards correction policy in this proposed rule.

3. Performance Standards for the FY 2024 Program Year

In section VII.C.1, we propose to use FY 2019 data for the baseline period for the FY 2024 program year. Based on this baseline period, we estimate that the performance standards would have the numerical values noted in Table 32. We note that these values represent estimates based on the most recently available data, and that we will update the numerical values in the FY 2022 SNF PPS final rule.

TABLE 32—ESTIMATED FY 2024 SNF VBP PROGRAM PERFORMANCE STANDARDS

Measure ID	Measure description	Achievement threshold	Benchmark
SNFRM	SNF 30-Day All-Cause Readmission Measure (NQF #2510)	0.79270	0.83028

E. SNF VBP Performance Scoring

We refer readers to the FY 2017 SNF PPS final rule (81 FR 52000 through 52005) for a detailed discussion of the scoring methodology that we have finalized for the Program. We also refer readers to the FY 2018 SNF PPS final rule (82 FR 36614 through 36616) for discussion of the rounding policy we adopted. We also refer readers to the FY 2019 SNF PPS final rule (83 FR 39278 through 39281), where we adopted: (1) A scoring policy for SNFs without sufficient baseline period data, (2) a scoring adjustment for low-volume SNFs, and (3) an extraordinary circumstances exception policy.

In section VII.B.3. of this proposed rule, we are proposing to suppress the SNFRM for the FY 2022 program year. If finalized, for all SNFs participating in the FY 2022 SNF VBP program, we will use the previously finalized performance period and baseline period to calculate each SNF's RSRR for the SNFRM. Then, we would assign all SNFs a performance score of zero. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We would then apply the Low-Volume Adjustment policy as previously finalized. That is, if a SNF has fewer than 25 eligible stays during the performance period for a

program year we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier. SNFs will not be ranked for the FY 2022 SNF VBP program.

F. SNF Value-Based Incentive Payments

We refer readers to the FY 2018 SNF PPS final rule (82 FR 36616 through 36621) for discussion of the exchange function methodology that we have adopted for the Program, as well as the specific form of the exchange function (logistic, or S-shaped curve) that we finalized, and the payback percentage of 60 percent. We adopted these policies for FY 2019 and subsequent fiscal years.

We also discussed the process that we undertake for reducing SNFs' adjusted Federal per diem rates under the Medicare SNF PPS and awarding value-based incentive payments in the FY 2019 SNF PPS final rule (83 FR 39281 through 39282).

In section VII.B.3. of this proposed rule, we are proposing to suppress the SNFRM for the FY 2022 program year. If finalized, for all SNFs participating in the FY 2022 SNF VBP program, we will use the previously finalized performance period and baseline period to calculate each SNF's RSRR for the SNFRM. Then, we would assign all SNFs a performance score of zero. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. SNFs will not be ranked for the FY 2022 SNF VBP program. We would then apply the Low-Volume Adjustment policy as previously finalized. That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier.

We are also proposing to reduce each participating SNF's adjusted Federal per diem rate for FY 2022 by 2 percentage points and to award each participating SNF 60 percent of that 2 percent withhold, resulting in a 1.2 percent payback for the FY 2022 program year. We believe this continued application of the 2 percent withhold is required under section 1888(h)(5)(C)(ii)(III) of the Act and that a payback percentage that is spread evenly across all SNFs is the most equitable way to reduce the impact of the withhold in light of our proposal to award a performance score of zero to all SNFs. Those SNFs subject to the Low-Volume Adjustment policy which would receive 100 percent of their 2 percent withhold per the previously finalized policy, increasing the overall payback percentage to an estimated 62.9 percent. We propose to codify this policy at § 413.338(g).

We invite public comment on this proposed change to the SNF VBP payment policy for the FY 2022 program year.

G. Public Reporting on the Nursing Home Compare Website or a Successor Website

1. Background

Section 1888(g)(6) of the Act requires the Secretary to establish procedures to make SNFs' performance information on SNF VBP Program measures available to the public on the Nursing Home Compare website or a successor website, and to provide SNFs an opportunity to review and submit corrections to that information prior to its publication. We began publishing SNFs' performance information on the SNFRM in accordance with this directive and the statutory deadline of October 1, 2017. In December 2020, we retired the Nursing Home Compare website and are now using the Provider Data Catalogue website (*https://data.cms.gov/provider-data/*) to make quality data available to the public, including SNF VBP performance information.

Additionally, section 1888(h)(9)(A) of the Act requires the Secretary to make available to the public certain information on SNFs' performance under the SNF VBP Program, including SNF performance scores and their ranking. Section 1888(h)(9)(B) of the Act requires the Secretary to post aggregate information on the Program, including the range of SNF performance scores and the number of SNFs receiving value-based incentive payments, and the range and total amount of those payments.

In the FY 2017 SNF PPS final rule (81 FR 52009), we discussed the statutory requirements governing public reporting of SNFs' performance information under the SNF VBP Program. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF VBP Program performance information on the Nursing Home Compare or successor website after SNFs have had an opportunity to review and submit corrections to that information under the two-phase Review and Correction process that we adopted in the FY 2017 SNF PPS final rule (81 FR 52007 through 52009) and for which we adopted additional requirements in the FY 2018 SNF PPS final rule. In the FY 2018 SNF PPS final rule, we also adopted requirements to rank SNFs and adopted data elements that we will include in the ranking to provide consumers and stakeholders with the necessary information to evaluate SNFs' performance under the Program (82 FR 36623).

In section VII.B.3. of this proposed rule, we are proposing to suppress the SNFRM for the FY 2022 program year. Under this proposal, for all SNFs participating in the FY 2022 SNF VBP program, we will use the previously finalized performance period and baseline period to calculate each SNF's RSRR for the SNFRM. Then, we would assign all SNFs a performance score of zero. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We would then apply the Low-Volume Adjustment policy as previously finalized. That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier.

While we will publicly report the SNFRM rates for the FY 2022 program year, we will make clear in the public presentation of those data that we are suppressing the use of those data for purposes of scoring and payment adjustments in the FY 2022 SNF VBP given the significant changes in SNF patient case volume and facility-level case mix described above. SNFs will not be ranked for the FY 2022 SNF VBP program.

2. Data Suppression Policy for Low-Volume SNFs

In the FY 2020 SNF PPS final rule (84 FR 38823 through 38824), we adopted a data suppression policy for low-volume SNF performance information. Specifically, we finalized that we will suppress the SNF performance information available to display as follows: (1) If a SNF has fewer than 25 eligible stays during the baseline period for a program year, we will not display the baseline risk-standardized readmission rate (RSRR) or improvement score, although we will still display the performance period RSRR, achievement score, and total performance score if the SNF had sufficient data during the performance period; (2) if a SNF has fewer than 25 eligible stays during the performance period for a program year and receives an assigned SNF performance score as a result, we will report the assigned SNF performance score and we will not display the performance period RSRR, the achievement score, or improvement score; and (3) if a SNF has zero eligible cases during the performance period for a program year, we will not display any information for that SNF. We codified

this policy in the FY 2021 SNF PPS final rule (85 FR 47626) at § 413.338(e)(3)(i), (ii), and (iii).

In section VII.B.3. of this proposed rule, we are proposing to suppress the SNFRM for the FY 2022 program year. Under this proposal, for all SNFs participating in the FY 2022 SNF VBP program, we will use the previously finalized performance period and baseline period to calculate each SNF's RSRR for the SNFRM. Then, we would assign all SNFs a performance score of zero. This would result in all participating SNFs receiving an identical performance score, as well as an identical incentive payment multiplier. We would then apply the Low-Volume Adjustment policy as previously finalized. That is, if a SNF has fewer than 25 eligible stays during the performance period for a program year we will assign that SNF a performance score resulting in a net-neutral payment incentive multiplier. SNFs will not be ranked for the FY 2022 SNF VBP program.

3. Public Reporting of SNF VBP Performance Information on Nursing Home Compare or a Successor Website

Section 1888(h)(9)(A) of the Act requires that the Secretary make available to the public on the Nursing Home Compare website or a successor website information regarding the performance of individual SNFs for a fiscal year, including the performance score for each SNF for the fiscal year and each SNF's ranking, as determined under section 1888(h)(4)(B) of the Act. Additionally, section 1888(h)(9)(B) of the Act requires that the Secretary periodically post aggregate information on the SNF VBP Program on the Nursing Home Compare website or a successor website, including the range of SNF performance scores, and the number of SNFs receiving value-based incentive payments and the range and total amount of those payments. In the FY 2018 SNF PPS final rule (82 FR 36622 through 36623), we finalized our policy to publish SNF measure performance information under the SNF VBP Program on Nursing Home Compare.

In the FY 2021 SNF PPS final rule (85 FR 47626), we finalized an amendment to § 413.338(e)(3) to reflect that we will publicly report SNF performance information on the Nursing Home Compare website or a successor website located at *https://www.medicare.gov/care-compare/.* We are not proposing any changes to the public reporting policies in this proposed rule.

H. Proposal To Update and Codify the Phase One Review and Correction Claims ''Snapshot'' Policy

In the FY 2017 SNF PPS final rule (81 FR 52007 through 52009), we adopted a two-phase review and corrections process for SNFs' quality measure data that will be made public under section 1888(g)(6) of the Act and SNF performance information that will be made public under section 1888(h)(9) of the Act. We detailed the process for requesting Phase One corrections and finalized a policy whereby we would accept Phase One corrections to a quarterly report provided during a calendar year until the following March 31.

In the FY 2020 SNF PPS final rule (84 FR 38824 through 38835), we updated this policy to reflect a 30-day Phase One Review and Correction deadline rather than through March 31st following receipt of the performance period quality measure quarterly report.

In the FY 2021 SNF PPS final rule (85 FR 47626 through 47627), we updated the 30-day deadline for Phase One Review and Correction and codified the policy at § 413.338(e)(1). Under the updated policy, beginning with the baseline period quality report issued on or after October 1, 2020 that contains the baseline period measure rate and underlying claim information used to calculate the measure rate for the applicable program year, SNFs have 30 days following the date that CMS provides those reports to review and submit corrections to the data contained in those reports. We also stated that if the issuance dates of these reports are significantly delayed or need to be shifted for any reason, we would notify SNFs through routine communication channels including, but not limited to memos, emails, and notices on the CMS SNF VBP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page.*

We are now proposing to include a Phase One Review and Correction claims ''snapshot'' policy beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021. This proposed policy would limit the Phase One Review and Correction to errors made by CMS or its contractors when calculating a SNF's readmission measure rate and will not allow corrections to the underlying administrative claims data used to calculate those rates. Under this proposed policy, the administrative claims data we use to calculate a SNF's readmission measure rate for purposes of a baseline period or performance period for a given SNF VBP program year would be held constant (that is, frozen in a ''snapshot'') from the time we extract it for that purpose. This proposal would align the review and correction policy for the SNF VBP Program with the review and correction policy we have adopted for other value-based purchasing programs, including the Hospital Readmissions Reduction Program (HRRP), Hospital-Acquired Condition (HAC) Reduction Program, and Hospital Value-Based Purchasing (VBP) Program.

For purposes of this program, we propose to calculate the SNF readmission measure rates using a static ''snapshot'' of claims updated as of 3 months following the last index SNF admission in the applicable baseline period or performance period. The source of the administrative claims data we use to calculate the SNF readmission measure is the Medicare Provider Analysis and Review (MedPAR). For example, if the last index SNF admission date for the applicable baseline period or performance period is September 30th, 2019, we would extract the administrative claims data from the MedPAR file as that data exists on December 31st, 2019. SNFs would then receive their SNF readmission measure rate and accompanying stay-level information in their confidential quality measure quarterly reports, and they would have an opportunity to review and submit corrections to our calculations as part of the Phase One corrections process. SNFs, however, would not be able to correct any of the underlying administrative claims data (for example, a SNF discharge destination code) we use to generate the measure rate.

The use of a data ''snapshot'' enables us to provide as timely quality data as possible, both to SNFs for the purpose of quality improvement and to the public for the purpose of transparency. After the claims ''snapshot'' is taken through our extraction of the data from MedPAR, it takes several months to incorporate other data needed for the SNF readmission measure calculations, generate and check the calculations, as well as program, populate, and deliver the confidential quarterly reports and accompanying data to SNFs. Because several months lead time is necessary after acquiring the input data to generate these calculations, if we were to delay our data extraction point beyond the date that is 3 months after the last SNF index admission attributable to a baseline period or performance period, we believe this would create an

unacceptably long delay both for SNFs to receive timely data for quality improvement and transparency, and, incentive payments for purposes of this program. Therefore, we believe that a 3-month claims ''run-out'' period between the date of the last SNF index admission and the date of the data extraction is a reasonable period that allows SNFs time to correct their administrative claims or add any missing claims before those claims are used for measure calculation purposes while enabling us to timely calculate the measure. If unforeseen circumstances require the use of additional months of claims ''run-out'', that is, more than 3 months, we would notify SNFs through routine communication channels including, but not limited to, memos, emails, quarterly reports and notices on the CMS SNF VBP website at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/SNF-VBP/SNF-VBP-Page.*

We believe this proposed policy would address both fairness and operational concerns associated with calculating measure rates and would provide consistency across value-based purchasing programs.

We are also proposing to codify this policy in our regulations by revising § 413.338(e)(1) to remove the policies that would no longer be applicable beginning October 1, 2021 and state the newly proposed policy that would be effective, if finalized, on October 1, 2021.

We invite public comment on this proposal to update the Phase One Review and Correction policy.

I. Proposal To Update the Instructions for Requesting an ECE in § 413.338(d)(4)(ii) of the SNF VBP Regulations

We are proposing to update the instructions for a SNF to request an extraordinary circumstances exception (ECE). Specifically, we are proposing to update the email address that a SNF must use to send the request, as well as the URL for our QualityNet website from *QualityNet.org* to *QualityNet.cms.gov*. We are also proposing to remove the separate reference to newspapers because newspapers are already included in the broader term ''media articles.'' We are proposing to update § 413.338(d)(4)(ii) of our regulations to reflect these changes.

We invite public comment on this proposal.

VIII. Collection of Information Requirements

This proposed rule would not impose any new or revised ''collection of information'' requirements or burden as it pertains to CMS. For the purpose of this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the Paperwork Reduction Act of 1995's (PRA) (44 U.S.C. 3501 *et seq.*) implementing regulations. Consequently, this rule is not subject to the requirements of the PRA.

We propose in section VI.C.1. of this proposed rule, the SNF HAIs Requiring Hospitalization measure beginning with the FY 2023 SNF QRP. All claims-based measures are calculated using data that are already reported to the Medicare program for payment purposes. Since the data source for this quality measure is Medicare fee-for-service claims, there is no additional burden for providers.

In section VI.C.2. of this proposed rule, we propose that SNFs submit data on the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2023 SNF QRP. We note that the CDC would account for the burden associated with the COVID–19 Vaccination Coverage among HCP measure collection under OMB control number 0920–1317 (expiration January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986) (NCVIA).[112] We refer readers to section X.A.5. of this proposed rule, where CMS has provided an estimate of the burden and cost to SNFs, and note that the CDC will include it in a revised information collection request for 0920–1317.

In section VI.C.3. of this proposed rule, we are proposing to update the Transfer of Health (TOH) Information to the Patient—Post Acute Care (PAC) measure to exclude residents discharged home under the care of an organized home health service or hospice. This measure was adopted in the FY 2020 SNF PPS final rule (84 FR 38728) and the associated burden was accounted for in OMB 0938–1140 (expiration November 30, 2022). The proposed update would not affect the information collection burden already established.

In section VI.G.3. of this proposed rule, we are proposing that SNFs submit data on the COVID–19 Vaccination among HCP measure through the CDC/National Healthcare Safety Network (NHSN). The NHSN is a secure, internet-based surveillance system maintained by the CDC and provided free of charge to healthcare facilities including SNFs.

While the NHSN is currently not utilized by SNFs for purposes of meeting the SNF QRP requirements, nursing homes were enrolled in the NHSN in 2020 and are currently submitting mandatory COVID–19 data through the Long-term Care Facility COVID–19 module (*https://www.cdc.gov/nhsn/ltc/covid19/index.html*). As such, there is no additional information collection burden related to the onboarding and training of SNF providers to utilize this system. In section VII.B.3. of this proposed rule, we are proposing to suppress the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM) for the FY 2022 SNF VBP Program Year. Because the data source for this quality measure is Medicare fee-for-service claims, there is no additional burden for SNFs. All claims-based measures can be calculated based on data that are already reported to the Medicare program for payment purposes.

IX. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

X. Economic Analyses

A. Regulatory Impact Analysis

1. Statement of Need

This proposed rule updates the FY 2022 SNF prospective payment rates as required under section 1888(e)(4)(E) of the Act. It also responds to section 1888(e)(4)(H) of the Act, which requires the Secretary to provide for publication in the **Federal Register** before the August 1 that precedes the start of each FY, the unadjusted Federal per diem rates, the case-mix classification system, and the factors to be applied in making the area wage adjustment. As these statutory provisions prescribe a detailed methodology for calculating and disseminating payment rates under the SNF PPS, we do not have the discretion

[112] Section 321 of the NCVIA provides the PRA waiver for activities that come under the NCVIA, including those in the NCVIA at section 2102 of the Public Health Service Act (42 U.S.C. 300aa–2). Section 321 is not codified in the U.S. Code, but can be found in a note at 42 U.S.C. 300aa–1.

to adopt an alternative approach on these issues.

2. Introduction

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA, September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA, March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant rule, under section 3(f)(1) of Executive Order 12866. Accordingly, we have prepared a regulatory impact analysis (RIA) as further discussed below. Also, the rule has been reviewed by OMB.

3. Overall Impacts

This rule would update the SNF PPS rates contained in the SNF PPS final rule for FY 2021 (85 FR 47594). We estimate that the aggregate impact would be an increase of approximately $444 million in Part A payments to SNFs in FY 2022. This reflects a $445 million increase from the update to the payment rates and a $1.2 million decrease due to the proposed reduction to the SNF PPS rates to account for the recently excluded blood-clotting factors (and items and services related to the furnishing of such factors) in section 1888(e)(2)(A)(iii)(VI) of the Act. We note that these impact numbers do not incorporate the SNF VBP reductions that we estimate would total $191.64 million in FY 2022. We would note that events may occur to limit the scope or accuracy of our impact analysis, as this analysis is future-oriented, and thus, very susceptible to forecasting errors due to events that may occur within the assessed impact time period.

In accordance with sections 1888(e)(4)(E) and (e)(5) of the Act and implementing regulations at § 413.337(d), we would update the FY 2021 payment rates by a factor equal to the market basket index percentage change reduced by the forecast error adjustment and the MFP adjustment to determine the payment rates for FY 2022. The impact to Medicare is included in the total column of Table 33. In proposing the SNF PPS rates for FY 2022, we are proposing a number of standard annual revisions and clarifications mentioned elsewhere in this proposed rule (for example, the proposed update to the wage and market basket indexes used for adjusting the Federal rates).

The annual update proposed in this rule would apply to SNF PPS payments in FY 2022. Accordingly, the analysis of the impact of the annual update that follows only describes the impact of this single year. Furthermore, in accordance with the requirements of the Act, we will publish a rule or notice for each subsequent FY that will provide for an update to the payment rates and include an associated impact analysis.

4. Detailed Economic Analysis

The FY 2022 SNF PPS payment impacts appear in Table 33. Using the most recently available data, in this case FY 2020, we apply the current FY 2021 CMIs, wage index and labor-related share value to the number of payment days to simulate FY 2021 payments. Then, using the same FY 2020 data, we apply the proposed FY 2022 CMIs, wage index and labor-related share value to simulate FY 2022 payments. We would note that, given that this same data is being used for both parts of this calculation, as compared to other analyses discussed in this proposed rule which compare data from FY 2020 to data from other fiscal years, any issues discussed throughout this proposed rule with regard to data collected in FY 2020 would not cause any difference in this economic analysis. We tabulate the resulting payments according to the classifications in Table 33 (for example, facility type, geographic region, facility ownership), and compare the simulated FY 2021 payments to the simulated FY 2022 payments to determine the overall impact. The breakdown of the various categories of data in Table 33 follows:

- The first column shows the breakdown of all SNFs by urban or rural status, hospital-based or freestanding status, census region, and ownership.
- The first row of figures describes the estimated effects of the various proposed changes on all facilities. The next six rows show the effects on facilities split by hospital-based, freestanding, urban, and rural categories. The next nineteen rows show the effects on facilities by urban versus rural status by census region. The last three rows show the effects on facilities by ownership (that is, government, profit, and non-profit status).
- The second column shows the number of facilities in the impact database.
- The third column shows the effect of the proposed annual update to the wage index. This represents the effect of using the most recent wage data available. The total impact of this change is 0.0 percent; however, there are distributional effects of the proposed change.
- The fourth column shows the effect of all of the changes on the FY 2022 payments. The proposed update of 1.3 percent is constant for all providers and, though not shown individually, is included in the total column. It is projected that aggregate payments would increase by 1.3 percent, assuming facilities do not change their care delivery and billing practices in response.

As illustrated in Table 33, the combined effects of all of the changes vary by specific types of providers and by location. For example, due to changes in this proposed rule, rural providers would experience a 1.8 percent increase in FY 2022 total payments. Finally, we note that we did not include in Table 33 the distributional impacts associated with the blood-clotting factor exclusion because the reduction is so minor that it does not have any visible effect on the distributional impacts included in the Table 33.

TABLE 33—IMPACT TO THE SNF PPS FOR FY 2022

Provider characteristics	Number providers	Update wage data (%)	Total change (%)
Group:			
Total	15,440	0.0	1.3

TABLE 33—IMPACT TO THE SNF PPS FOR FY 2022—Continued

Provider characteristics	Number providers	Update wage data (%)	Total change (%)
Urban	10,887	−0.1	1.2
Rural	4,553	0.4	1.8
Hospital-based urban	385	−0.2	1.1
Freestanding urban	10,502	−0.1	1.2
Hospital-based rural	451	0.3	1.6
Freestanding rural	4,102	0.4	1.7
Urban by region:			
New England	742	−0.7	0.6
Middle Atlantic	1,447	−0.5	0.8
South Atlantic	1,820	0.4	1.7
East North Central	2,145	−0.2	1.1
East South Central	539	−0.4	0.9
West North Central	919	0.4	1.7
West South Central	1,342	−0.3	1.0
Mountain	536	0.1	1.4
Pacific	1,391	0.2	1.5
Outlying	6	0.4	1.7
Rural by region:			
New England	129	−0.9	0.4
Middle Atlantic	245	0.5	1.8
South Atlantic	597	1.2	2.5
East North Central	909	0.5	1.8
East South Central	526	−0.1	1.2
West North Central	1,058	−0.3	1.0
West South Central	756	0.4	1.7
Mountain	222	0.5	1.8
Pacific	111	0.3	1.6
Ownership:			
For profit	10,809	0.0	1.3
Non-profit	3,637	0.0	1.3
Government	994	0.2	1.5

Note: The Total column includes the proposed FY 2022 1.3 percent market basket increase factor. Additionally, we found no SNFs in rural outlying areas.

5. Impacts for the SNF QRP for FY 2022

Estimated impacts for the SNF QRP are based on analysis discussed in section VIII.B. of this proposed rule. The proposed SNF QRP requirements add no additional burden to the active collection under OMB control number #0938–1140 (CMS–10387; expiration November 30, 2022).

In accordance with section 1888(e)(6)(A)(i) of the Act, the Secretary must reduce by 2 percentage points the annual payment update applicable to a SNF for a fiscal year if the SNF does not comply with the requirements of the SNF QRP for that fiscal year. In section VI.A. of this proposed rule, we discuss the method for applying the 2 percentage point reduction to SNFs that fail to meet the SNF QRP requirements. As discussed in section VI.C. of this proposed rule, we are proposing to add two new measures to the SNF QRP beginning with the FY 2023 SNF QRP: SNF Healthcare-Associated Infections Requiring Hospitalization Measure (SNF–HAI) and the COVID–19 Vaccination Coverage among Healthcare Personnel measure. The SNF–HAI measure is a claims-based measure, and therefore, would impose no additional burden to the SNFs.

We believe that the burden associated with the SNF QRP is the time and effort associated with complying with the non-claims-based measures requirements of the SNF QRP. Although the burden associated with the COVID–19 Vaccination Coverage among HCP measure is not accounted for under the CDC PRA package currently approved under OMB control number 0920–1317 due to the NCVIA waiver the cost and burden is discussed here and will be included in a revised information collection request for 0920–1317.

Consistent with the CDC's experience of collecting data using the NHSN, we estimate that it would take each SNF an average of 1 hour per month to collect data for the COVID–19 Vaccination Coverage among HCP measure and enter it into NHSN. We have estimated the time to complete this entire activity, since it could vary based on provider systems and staff availability. We believe it would take an administrative assistant from 45 minutes up to 1 hour and 15 minutes to enter this data into NHSN. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages from the U.S. Bureau of Labor Statistics' May 2019 National Occupational Employment and Wage Estimates.[113] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table 34.

[113] *https://www.bls.gov/oes/current/oes_nat.htm.* Accessed on March 30, 2021.

TABLE 34—U.S. BUREAU OF LABOR AND STATISTICS' MAY 2019 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Overhead and fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Administrative Assistant	43–6013	$18.31	$18.31	$36.62

Based on this time range, it would cost each SNF between $27.47 and $45.78 each month or an average cost of $36.62 each month, and between $329.64 and $549.36 each year, or an average cost of $439.44 each year. We believe the data submission for the COVID–19 Vaccination Coverage among HCP measure would cause SNFs to incur additional average burden of 12 hours per year for each SNF and a total annual burden of 180,936 hours for all SNFs. The estimated annual cost across all 15,078 SNFs in the U.S. for the submission of the COVID–19 Vaccination Coverage among HCP measure would be between $4,970,312 and $8,283,250.08, and an average of $6,625,872.

We recognize that many SNFs may also be reporting other COVID–19 data to HHS. However, we believe the benefits of reporting data on the COVID–19 Vaccination Coverage among HCP measure to assess whether SNFs are taking steps to limit the spread of COVID–19 among their HCP, reduce the risk of transmission of COVID–19 within their facilities, and to help sustain the ability of SNFs to continue serving their communities throughout the PHE and beyond outweigh the costs of reporting. We welcome comments on the estimated time to collect data and enter it into NHSN.

6. Impacts for the SNF VBP Program

The estimated impacts of the FY 2022 SNF VBP Program are based on historical data and appear in Table 35. We modeled SNF performance in the Program using SNFRM data from FY 2018 as the baseline period and an 8-month period from February 1, 2019 through September 30, 2019 as the performance period. Additionally, we modeled a logistic exchange function with a payback percentage of 60 percent, as we finalized in the FY 2018 SNF PPS final rule (82 FR 36619 through 36621), though we note that the 60 percent payback percentage for FY 2022 will be adjusted to account for the low-volume scoring adjustment that we adopted in the FY 2019 SNF PPS final rule (83 FR 39278 through 39280). However, in section VII.B.3. of this proposed rule, we are proposing to suppress the SNFRM for the FY 2022 program year. If finalized, we will award each participating SNF 60 percent of their 2 percent withhold, except those SNFs subject to the low-volume scoring adjustment, which would receive 100 percent of their 2 percent withhold. We estimated that the low-volume scoring adjustment would increase the 60 percent payback percentage for FY 2022 by approximately 2.9 percentage points (or $16.4 million), resulting in a payback percentage for FY 2022 that is 62.9 percent of the estimated $516.2 million in withheld funds for that fiscal year. Based on the 60 percent payback percentage (as modified by the low-volume scoring adjustment), we estimated that we will redistribute approximately $324.5 million in value-based incentive payments to SNFs in FY 2022, which means that the SNF VBP Program is estimated to result in approximately $191.6 million in savings to the Medicare Program in FY 2022.

Our detailed analysis of the estimated impacts of the FY 2022 SNF VBP Program follows in Table 35.

TABLE 35—SNF VBP PROGRAM ESTIMATED IMPACTS FOR FY 2022

Characteristic	Number of facilities	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total payment after applying incentives
Group:					
Total	15,026	19.90	1.4545	0.99426	100
Urban	10,845	19.94	1.1528	0.99379	85.29
Rural	4,181	19.81	2.2371	0.99547	14.71
Hospital-based urban *	284	19.68	1.1794	0.99383	1.79
Freestanding urban *	10,520	19.95	1.1423	0.99377	83.47
Hospital-based rural *	182	19.55	2.6050	0.99604	0.43
Freestanding rural *	3,803	19.81	2.1749	0.99538	14.12
Urban by region:					
New England	744	20.10	0.8104	0.99326	5.38
Middle Atlantic	1,462	19.78	0.7155	0.99311	16.57
South Atlantic	1,874	20.00	0.6407	0.99299	17.01
East North Central	2,065	20.08	1.3950	0.99417	13.32
East South Central	555	20.08	0.9471	0.99347	3.53
West North Central	923	19.92	2.1104	0.99528	4.23
West South Central	1,312	20.11	1.6811	0.99461	7.48
Mountain	523	19.56	1.4090	0.99419	3.72
Pacific	1,381	19.67	0.9702	0.99351	14.05
Outlying	6	20.96	2.5766	0.9960	0.00
Rural by region:					
New England	122	19.30	1.6896	0.99462	0.64
Middle Atlantic	210	19.53	1.1779	0.99383	0.90
South Atlantic	473	19.91	1.5144	0.99435	2.11
East North Central	895	19.69	1.8310	0.99484	3.35

TABLE 35—SNF VBP PROGRAM ESTIMATED IMPACTS FOR FY 2022—Continued

Characteristic	Number of facilities	Mean Risk-Standardized Readmission Rate (SNFRM) (%)	Mean performance score	Mean incentive multiplier	Percent of total payment after applying incentives
East South Central	495	20.06	1.1139	0.99373	2.26
West North Central	1,006	19.77	3.5653	0.99753	1.99
West South Central	689	20.13	2.5430	0.99595	2.18
Mountain	199	19.43	2.5378	0.99594	0.66
Pacific	91	19.22	1.5856	0.99446	0.60
Outlying	1	19.37	5.1533	1.0000	0.00
Ownership:					
Government	877	19.77	2.5149	0.9959	3.28
Profit	10,583	19.95	1.3693	0.9941	74.38
Non-Profit	3,566	19.81	1.4466	0.9943	22.33

* The group category which includes hospital-based/freestanding by urban/rural excludes 237 swing-bed SNFs.

7. Alternatives Considered

As described in this section, we estimated that the aggregate impact for FY 2022 under the SNF PPS would be an increase of approximately $444 million in Part A payments to SNFs. This reflects a $445 million increase from the update to the payment rates, and a $1.2 million decrease due to the proposed reduction to the SNF PPS rates to account for the recently excluded blood-clotting factors (and items and services related to the furnishing of such factors) in section 1888(e)(2)(A)(iii)(VI) of the Act.

Section 1888(e) of the Act establishes the SNF PPS for the payment of Medicare SNF services for cost reporting periods beginning on or after July 1, 1998. This section of the statute prescribes a detailed formula for calculating base payment rates under the SNF PPS, and does not provide for the use of any alternative methodology. It specifies that the base year cost data to be used for computing the SNF PPS payment rates must be from FY 1995 (October 1, 1994, through September 30, 1995). In accordance with the statute, we also incorporated a number of elements into the SNF PPS (for example, case-mix classification methodology, a market basket index, a wage index, and the urban and rural distinction used in the development or adjustment of the Federal rates). Further, section 1888(e)(4)(H) of the Act specifically requires us to disseminate the payment rates for each new FY through the **Federal Register**, and to do so before the August 1 that precedes the start of the new FY; accordingly, we are not pursuing alternatives for this process.

With regard to the alternatives considered related to the other provisions contained in this proposed rule, such as the proposed methodology for calculating the proportional reduction to the rates to account for the exclusion of blood clotting factors from SNF consolidated billing, we discuss any alternatives considered within those sections.

With regard to the proposed SNF VBP measure suppression policy, we discuss any alternatives considered within those sections.

8. Accounting Statement

As required by OMB Circular A–4 (available online at *https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/*), in Tables 36, 37 and 38, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule for FY 2022. Tables 33 and 36 provide our best estimate of the possible changes in Medicare payments under the SNF PPS as a result of the policies in this proposed rule, based on the data for 15,440 SNFs in our database. Tables 35 and 37 provide our best estimate of the possible changes in Medicare payments under the SNF VBP as a result of the policies we have proposed for this program. Tables 34 and 38 provide our best estimate of the additional cost to SNFs to submit the data for the SNF QRP as a result of the policies in this proposed rule.

TABLE 36—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES, FROM THE 2021 SNF PPS FISCAL YEAR TO THE 2022 SNF PPS FISCAL YEAR

Category	Transfers
Annualized Monetized Transfers	$444 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

* The net increase of $444 million in transfer payments is a result of the $445 million increase due to the proposed market basket increase of 1.3 percent, reduced by $1.2 million due to the proposed proportional reduction associated with excluding blood clotting factors from SNF consolidated billing.

TABLE 37—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2022 SNF VBP PROGRAM

Category	Transfers
Annualized Monetized Transfers	$324.5 million.*
From Whom To Whom?	Federal Government to SNF Medicare Providers.

* This estimate does not include the two percent reduction to SNFs' Medicare payments (estimated to be $516.15 million) required by statute.

TABLE 38—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FOR THE FY 2022 SNF QRP PROGRAM

Category	Transfers/Costs
Costs for SNFs to Submit Data for QRP	$6.6 million.*

*Costs associated with the submission of data for the COVID–19 Vaccination Coverage among HCP will occur in FY 2022 and is likely to continue in future years.

9. Conclusion

This rule updates the SNF PPS rates contained in the SNF PPS final rule for FY 2021 (85 FR 47594). Based on the above, we estimate that the overall payments for SNFs under the SNF PPS in FY 2022 are projected to increase by approximately $444 million, or 1.3 percent, compared with those in FY 2021. We estimate that in FY 2022, SNFs in urban and rural areas would experience, on average, a 1.2 percent increase and 1.8 percent increase, respectively, in estimated payments compared with FY 2021. Providers in the rural South Atlantic region would experience the largest estimated increase in payments of approximately 2.5 percent. Providers in the rural New England region would experience the smallest estimated increase in payments of 0.4 percent.

B. Regulatory Flexibility Act Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most SNFs and most other providers and suppliers are small entities, either by reason of their non-profit status or by having revenues of $30 million or less in any 1 year. We utilized the revenues of individual SNF providers (from recent Medicare Cost Reports) to classify a small business, and not the revenue of a larger firm with which they may be affiliated. As a result, for the purposes of the RFA, we estimate that almost all SNFs are small entities as that term is used in the RFA, according to the Small Business Administration's latest size standards (NAICS 623110), with total revenues of $30 million or less in any 1 year. (For details, see the Small Business Administration's website at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/eligibility-size-standards*). In addition, approximately 20 percent of SNFs classified as small entities are non-profit organizations. Finally, individuals and states are not included in the definition of a small entity.

This rule would update the SNF PPS rates contained in the SNF PPS final rule for FY 2021 (85 FR 47594). Based on the above, we estimate that the aggregate impact for FY 2022 would be an increase of $444 million in payments to SNFs, resulting from the SNF market basket update to the payment rates, reduced by the impact of excluding blood clotting factors (and items and services related to the furnishing of such factors) from SNF consolidated billing under section 1888(e)(2)(A)(iii)(VI) and (e)(4)(G)(iii) of the Act. While it is projected in Table 33 that all providers would experience a net increase in payments, we note that some individual providers within the same region or group may experience different impacts on payments than others due to the distributional impact of the FY 2022 wage indexes and the degree of Medicare utilization.

Guidance issued by the Department of Health and Human Services on the proper assessment of the impact on small entities in rulemakings, utilizes a cost or revenue impact of 3 to 5 percent as a significance threshold under the RFA. In their March 2021 Report to Congress (available at *http://www.medpac.gov/docs/default-source/reports/mar21_medpac_ch7_sec.pdf*), MedPAC states that Medicare covers approximately 9 percent of total patient days in freestanding facilities and 16 percent of facility revenue (March 2020 MedPAC Report to Congress, 224). As indicated in Table 33, the effect on facilities is projected to be an aggregate positive impact of 1.3 percent for FY 2022. As the overall impact on the industry as a whole, and thus on small entities specifically, is less than the 3 to 5 percent threshold discussed previously, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small entities for FY 2022.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an MSA and has fewer than 100 beds. This proposed rule would affect small rural hospitals that: (1) Furnish SNF services under a swing-bed agreement or (2) have a hospital-based SNF. We anticipate that the impact on small rural hospitals would be a positive impact. Moreover, as noted in previous SNF PPS final rules (most recently, the one for FY 2021 (85 FR 47594)), the category of small rural hospitals is included within the analysis of the impact of this proposed rule on small entities in general. As indicated in Table 33, the effect on facilities for FY 2022 is projected to be an aggregate positive impact of 1.3 percent. As the overall impact on the industry as a whole is less than the 3 to 5 percent threshold discussed above, the Secretary has determined that this proposed rule would not have a significant impact on a substantial number of small rural hospitals for FY 2022.

C. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2021, that threshold is approximately $158 million. This proposed rule would impose no mandates on state, local, or tribal governments or on the private sector.

D. Federalism Analysis

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would have no substantial direct effect on state and local governments, preempt state law, or otherwise have federalism implications.

E. Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

F. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule would be the number of reviewers of this year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we believe that the number of commenters on last year's proposed rule is a fair estimate of the number of reviewers of this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of the proposed rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the national mean hourly wage data from the May 2019 BLS Occupational Employment Statistics (OES) for medical and health service managers (SOC 11–9111), we estimate that the cost of reviewing this rule is $110.74 per hour, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm.* Assuming an average reading speed, we estimate that it would take approximately 4 hours for the staff to review half of the proposed rule. For each SNF that reviews the rule, the estimated cost is $442.96 (4 hours × $110.74). Therefore, we estimate that the total cost of reviewing this regulation is $20,819.12 ($442.96 × 47 reviewers).

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 413

Principles of reasonable cost reimbursement; payment for end-stage renal disease services; optional prospectively determined payment rates for skilled nursing facilities; payment for acute kidney injury dialysis.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

■ 2. Amend § 411.15 by—

■ a. Revising paragraphs (p)(2)(xiii) through (xvi);

■ b. Redesignating paragraph (p)(2)(xvii) as (p)(2)(xviii); and

■ c. Adding new paragraph (p)(2)(xvii).

The revisions and addition read as follows:

§ 411.15 Particular services excluded from coverage.

* * * * *

(p) * * *

(2) * * *

(xiii) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(xiv) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(xv) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(xvi) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(xvii) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END–STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 4. Amend § 413.338 by revising paragraphs (d)(4)(ii) and (e)(1) and adding paragraph (g) to read as follows:

§ 413.338 Skilled nursing facility value-based purchasing program.

* * * * *

(d) * * *

(4) * * *

(ii) A SNF may request an exception within 90 days of the date that the extraordinary circumstances occurred by sending an email to the designated email address for SNF VBP ECE requests, which is *SNFVBP@rti.org.* The email must include a completed Extraordinary Circumstances Request form (available on *https://qualitynet.cms.gov/*) and any available evidence of the impact of the extraordinary circumstances on the care that the SNF furnished to patients including, but not limited to, photographs and media articles.

* * * * *

(e) * * *

(1) CMS will provide quarterly confidential feedback reports to SNFs on their performance on the SNF

readmission measure. Beginning with the baseline period and performance period quality measure quarterly reports issued on or after October 1, 2021, which contain the baseline period and performance period measure rates, respectively, SNFs will have 30 days following the date CMS provides each of these reports to review and submit corrections to the SNF readmission measure rates contained in that report. The administrative claims data used to calculate a SNF's readmission measure rates are not subject to review and correction under this paragraph (e)(1). All correction requests must be accompanied by appropriate evidence showing the basis for the correction to the SNF readmission measure rates.

* * * * *

(g) *Special rules for the FY 2022 SNF VBP Program.* (1) CMS will calculate a SNF readmission measure rate for each SNF based on its performance on the SNF readmission measure during the performance period specified by CMS for fiscal year 2022, but CMS will not calculate a performance score for any SNF using the methodology described in paragraphs (d)(1) and (2) of this section. CMS will instead assign a performance score of zero to each SNF, with the exception of those SNFs qualifying for the low-volume scoring adjustment described in paragraph (d)(3) of this section.

(2) CMS will calculate the value-based incentive payment adjustment factor for each SNF using a performance score of zero and will then calculate the value-based incentive payment amount for each SNF using the methodology described in paragraph (c)(2)(ii) of this section. CMS will then apply low-volume scoring adjustment described in paragraph (d)(3) of this section.

(3) CMS will provide confidential feedback reports to SNFs on their performance on the SNF readmission measure in accordance with paragraphs (e)(1) and (2) of this section.

(4) CMS will publicly report SNF performance on the SNF readmission measure in accordance with paragraph (e)(3) of this section.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 5. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 6. Amend § 489.20 by—

■ a. Revising paragraphs (s)(13) through (16);

■ b. Redesignating paragraph (s)(17) as paragraph (s)(18); and

■ c. Adding new paragraph (s)(17) to read as follows:

§ 489.20 Basis commitments.

* * * * *

(s) * * *

(13) Those chemotherapy items identified, as of July 1, 1999, by HCPCS codes J9000–J9020, J9040–J9151, J9170–J9185, J9200–J9201, J9206–J9208, J9211, J9230–J9245, and J9265–J9600, and as of January 1, 2004, by HCPCS codes A9522, A9523, A9533, and A9534 (as subsequently modified by CMS), and any additional chemotherapy items identified by CMS.

(14) Those chemotherapy administration services identified, as of July 1, 1999, by HCPCS codes 36260–36262, 36489, 36530–36535, 36640, 36823, and 96405–96542 (as subsequently modified by CMS), and any additional chemotherapy administration services identified by CMS.

(15) Those radioisotope services identified, as of July 1, 1999, by HCPCS codes 79030–79440 (as subsequently modified by CMS), and any additional radioisotope services identified by CMS.

(16) Those customized prosthetic devices (including artificial limbs and their components) identified, as of July 1, 1999, by HCPCS codes L5050–L5340, L5500–L5611, L5613–L5986, L5988, L6050–L6370, L6400–6880, L6920–L7274, and L7362–L7366 (as subsequently modified by CMS) and any additional customized prosthetic devices identified by CMS, which are delivered for a resident's use during a stay in the SNF and intended to be used by the resident after discharge from the SNF.

(17) Those blood clotting factors indicated for the treatment of patients with hemophilia and other bleeding disorders identified, as of July 1, 2020, by HCPCS codes J7170, J7175, J7177–J7183, J7185–J7190, J7192–J7195, J7198–J7203, J7205, and J7207–J7211 (as subsequently modified by CMS) and items and services related to the furnishing of such factors, and any additional blood clotting factors identified by CMS and items and services related to the furnishing of such factors.

* * * * *

Dated: March 29, 2021.

Elizabeth Richter,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 8, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–07556 Filed 4–8–21; 4:15 pm]

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